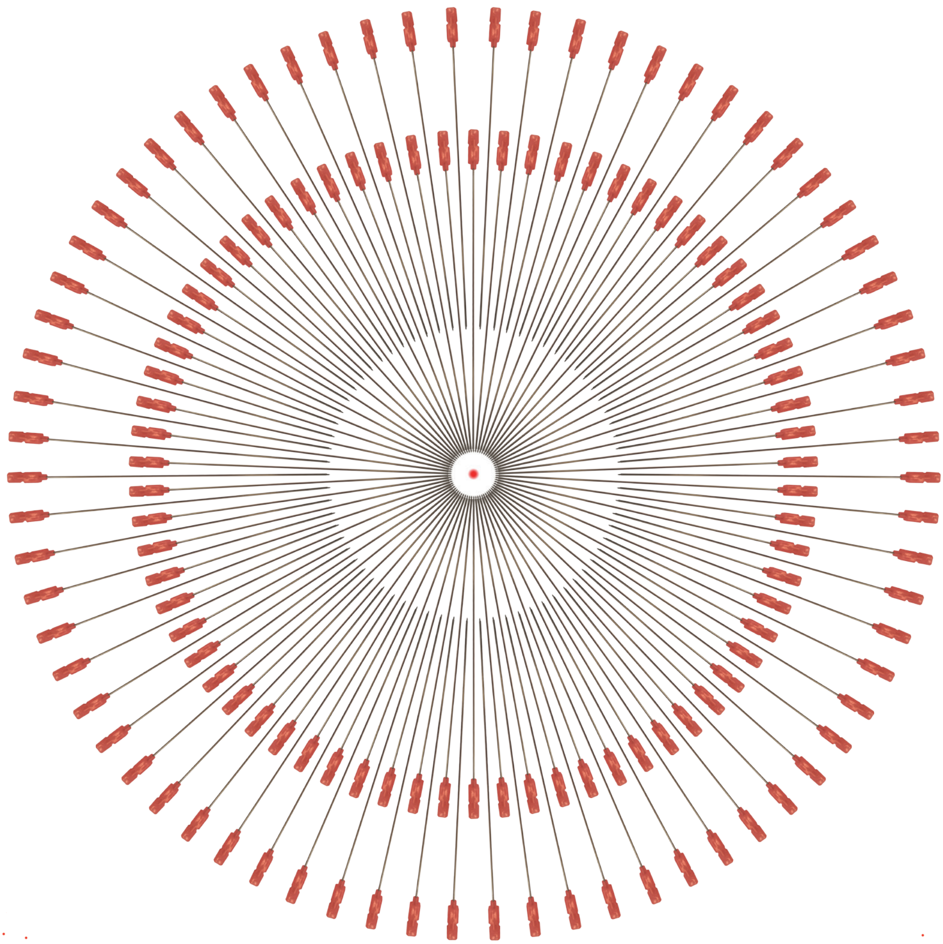
Impact of laser guidance in image-guided needle interventions



Maarten Kroes

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Colofon

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Voor mijn ouders

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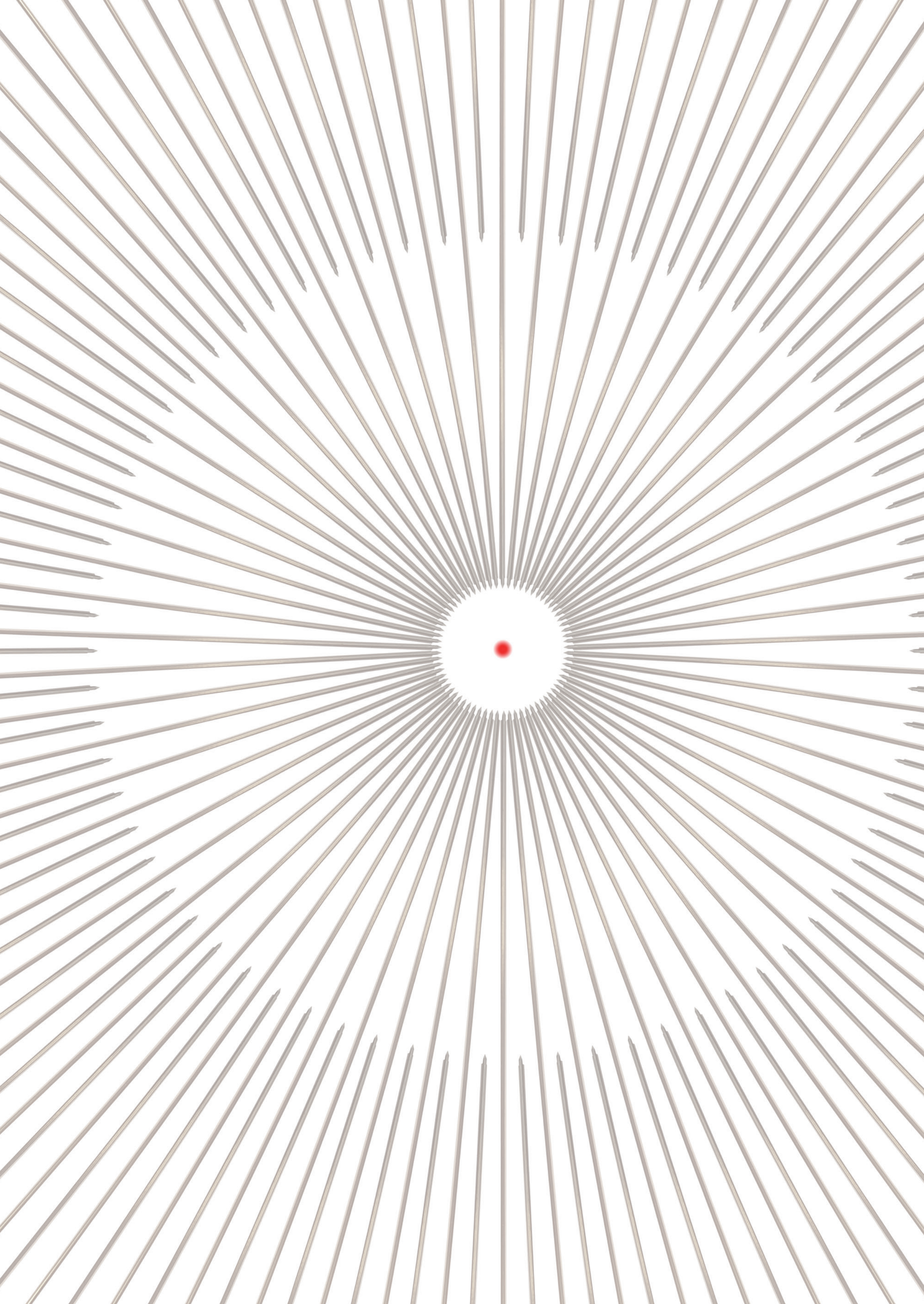

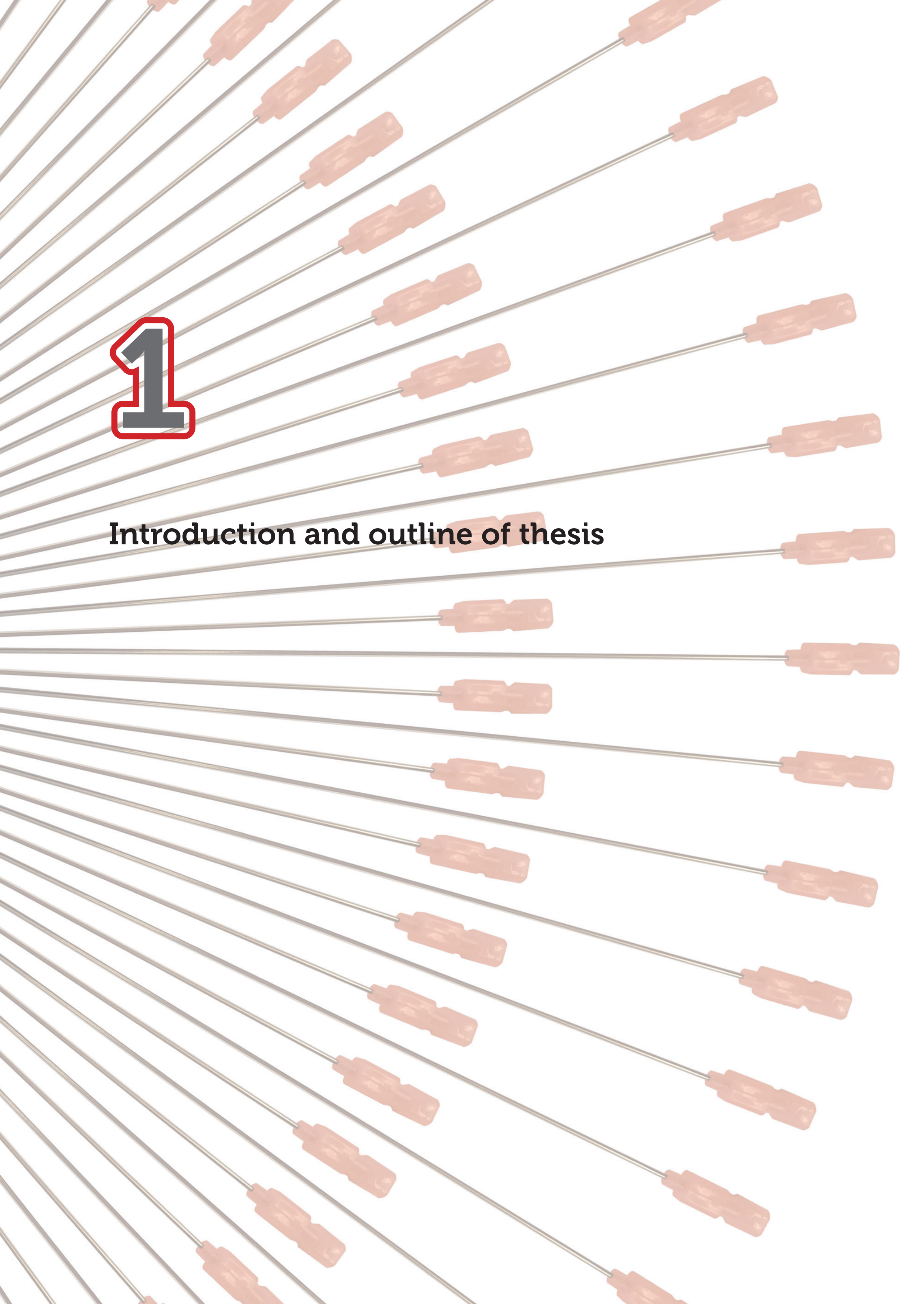

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Introduction and outline of thesis

PERCUTANEOUS NEEDLE INTERVENTIONS

Nonvascular percutaneous image-guided needle intervention is an often performed procedure to access suspicious lesions for diagnostic or therapeutic purposes. One of the first interventions was performed in 1954 by Wickbom, who used x-rays to place a long needle in the renal pelvis so as to inject contrast medium for diagnosis (1). Since then, percutaneous nonvascular image-guided interventions have evolved extensively with the arrival of new therapeutic techniques and imaging modalities.

For therapeutic purposes, needles can be placed in tissue which require ablation using several techniques. Treatment of liver tumours using radiofrequency (RF) ablation needles instead of open surgery was proposed in 1990 (2). During the past 20 years, RF ablation has expanded to other areas such as kidney, lung and bone tumours. There are several other ablation techniques where needles or devices are placed that can be used to destroy the tissue, like thermal, cryo- or laser-ablation and electroporation. These percutaneous needle interventions are a minimally invasive alternative to open surgical procedures. Not only do they allow patient treatment in less procedural time and hospital stay, but also provide alternatives to patients that are unsuitable for surgery.

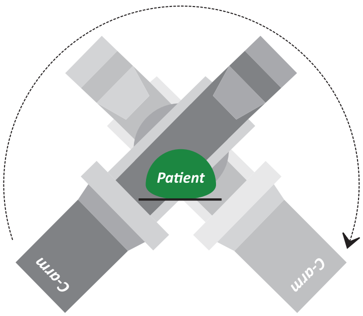
Accurate positioning of these type of needles do not solely rely on x-ray guidance as was the case in the 50s of the previous century. Nowadays, needle interventions are performed under guidance of ultrasound, fluoroscopy, computed tomography (CT), and magnetic resonance imaging (MRI). Of these techniques, MRI and ultrasound do not use ionizing radiation. However, MRI is very expensive and requires long acquisition times. Ultrasound on the other hand is cheap and provides real-time imaging, but can be impeded by limited spatial and contrast resolutions. Fusion technologies, combining MRI or CT with ultrasound are promising, but require extra investments. Therefore, despite the ionizing radiation, CT is often used for image-guided percutaneous nonvascular interventions as it is fast and provides 3D image datasets visualizing the target (3).

The impact of image-guided needle interventions on modern medicine has grown quickly since the first CT-guided biopsy in the late 1970s (4). Sharpe et al. showed a strong increase in CT-guided thoracic biopsies with a decreasing number of biopsies performed surgically and bronchoscopically (5). Furthermore, from the 1990s onwards, the number of nonvascular interventional radiologic procedures have doubled (6). Traditionally, the needle interventions were performed to diagnose or evaluate suspicious lesions. Today, these interventions are also performed as a therapy using thermal ablation, for monitoring response to therapy and detecting recurrences of metastatic disease (7, 8). Implicit in their more extensive application, these needle interventions are accompanied with an increase in complexity which affects procedure time, number of control scans and radiation dose (9). Navigational systems were introduced to improve the feasibility of these interventions. An example of such a navigational system is cone-beam CT guidance. The difference compared to the other navigation systems is the use of the angiography suite instead of the CT-room. In comparison to the conventional CT and CT-fluoroscopy guidance setups, the angiography suite is designed for interventions under sterile conditions, cone-beam CT provides a C-arm geometry with more working space and patient access, while the cone-beam CT guidance achieves a higher accuracy in double oblique needle punctures (10, 11).

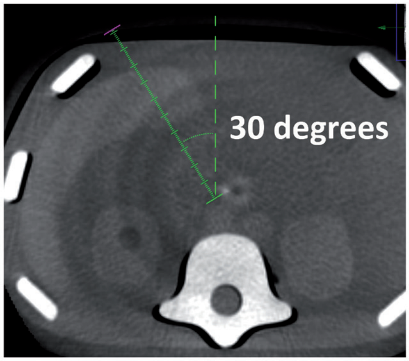
CONE-BEAM CT-GUIDANCE

During a cone-beam CT-scan, the C-arm rotates around the patient acquiring numerous x-ray projections, which are reconstructed to obtain a 3D volume with soft tissue information. The technique was already described in 1984 (12) but only became commercially available after the introduction of the flat panel detectors in the late 1990's (13). For percutaneous needle interventions a cone-beam CT scan is obtained to plan a needle path. The rotational capabilities of the C-arm combined with fluoroscopy guidance provide real-time feedback on the needle position with respect to the 3D volume and needle path planning (14).

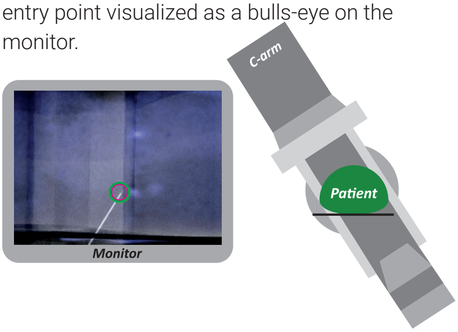
Step 1
Acquiring a cone-beam CT scan, the C-arm rotates around the patient acquiring numerous X-ray projections.



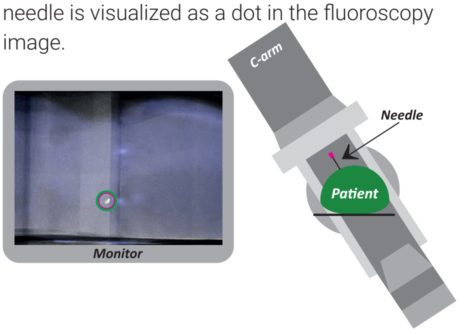
Step 2
Plan a needle path.
In this example a needle path of 30 degrees.



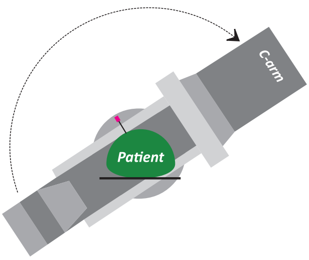
Step 3
Find and mark the entry point using fluoroscopy
- Place the C-arm in the entry point view
- Use needle and fluoroscopy to find the skin entry point visualized as a bulls-eye on the monitor.



Step 4
Position needle in angulation of the needle path planning
- The needle is positioned correctly when the needle is visualized as a dot in the fluoroscopy image.



Step 5
Rotate C-arm in progress view



Step 6
Progress needle until target is reached according to fluoroscopy images on the monitor

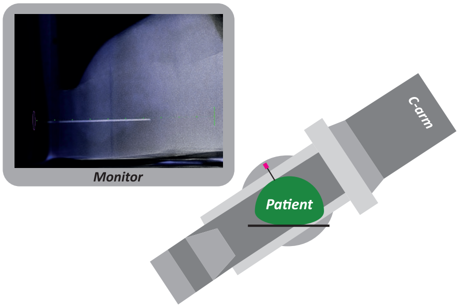


Figure 1.1: *A detailed visualization of the steps during CBCT-guided needle interventions.*

Two views are mainly used during fluoroscopy guidance to assist needle positioning. The entry point view, an overlay of entry and target point in a bull's-eye fashion, and the progress view, perpendicular to the entry point view. For a successful needle placement, the C-arm needs to be switched between these views to provide all the necessary information. The complete procedure is described by Figure 1.1. The challenge is to position the needle without switching too often between views and limiting the fluoroscopy use during needle manipulations. In our experience, needle manipulations often occur during fluoroscopy guidance resulting in the operator's hands inside the primary radiation beam (Figure 1.2). A similar drawback is present in needle guidance challenges for CT-fluoroscopy.

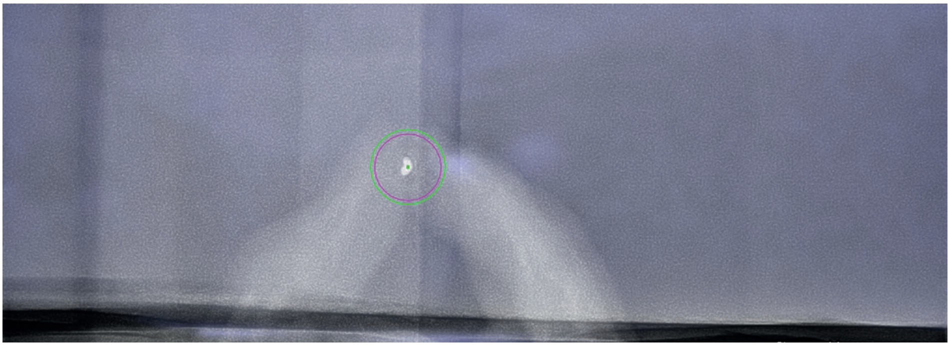


Figure 1.2: *Hand of operator inside primary radiation beam*

To limit radiation to the operator and patient, many different needle guidance devices were developed in the last decades. These systems range from a simple passive tool to support needles to remote controlled manipulators. Overall, these guidance devices can be divided into three categories: tracking systems, laser guidance, and needle holders.

GUIDANCE DEVICES

Tracking systems

Tracking systems supply continuous feedback to the operator on the position of the needle with respect to the imaged volume and position according to the planning. The requirements are to register the imaged (cone-beam) CT volume to the tracking system, and to continuously track the position of the needle with respect to this volume. There are two types of techniques: optical and electromagnetic tracking systems.

The *optical tracking techniques* require light-reflective or light-emitting radiopaque markers attached to the patient, which are visible in the scan and visible for the tracking device to enable registration. Markers are also attached to needle/needle holder. Examples of commercially available optical tracking systems are CAS-ONE (CAScination, Bern, Switzerland) (15) and CT-Guide (ActiViews, Wakefield, USA) (16). CT-Guide uses a small disposable sterile camera, which can be attached to the needle. A sterile sticker with colour codes and radiopaque markers inside is used to register the scan to the visuals made by the camera (16). These systems require an unobstructed line of sight between the camera and markers.

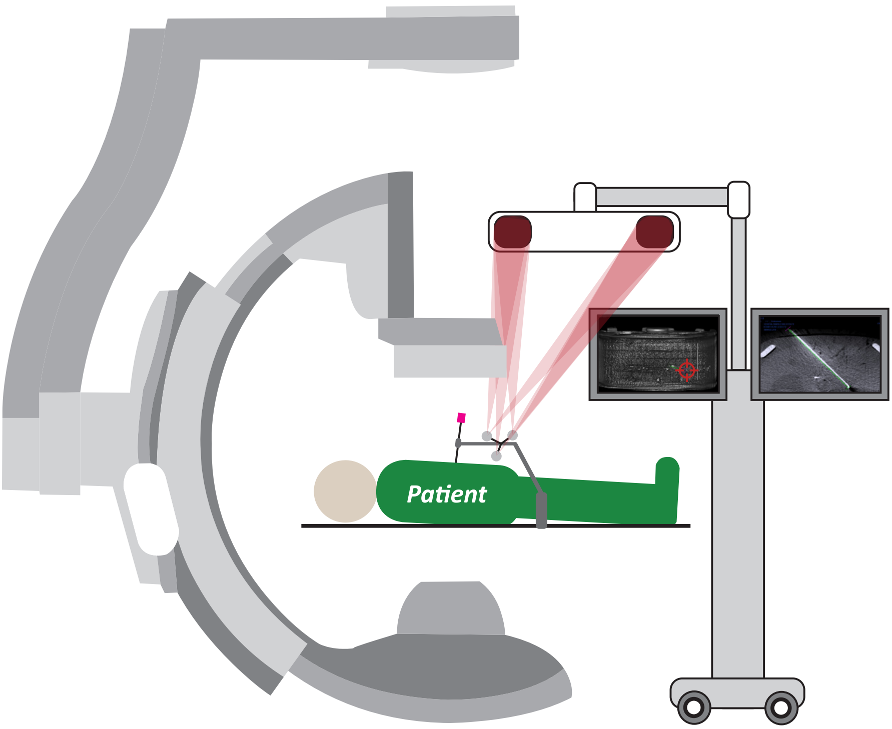


Figure 1.3: *Schematic presentation of an optical tracking system inside the angiography suite.*

Electromagnetic tracking systems use a generator for a magnetic field and electromagnetic sensors on the needle or holder consisting of one or multiple coils. For this technique the sensors no longer need to be in the line of sight; however, the presence of metallic objects can disturb the magnetic field resulting in registration errors. Examples of devices currently developed for percutaneous needle interventions using electromagnetic sensors are: iGuide CAPPA (CAS innovations, Erlangen, Germany) (17) and CT-NAVIGATION (IMACTIS, La Tronche, France) (18). The iGuide CAPPA system use a magnetic field generator mounted on the operating table and require needles with the electromagnetic sensor inside the tip, while for CT-NAVIGATION a generator is positioned on the patient near the puncture site and uses a needle holder with an electromagnetic sensor inside.

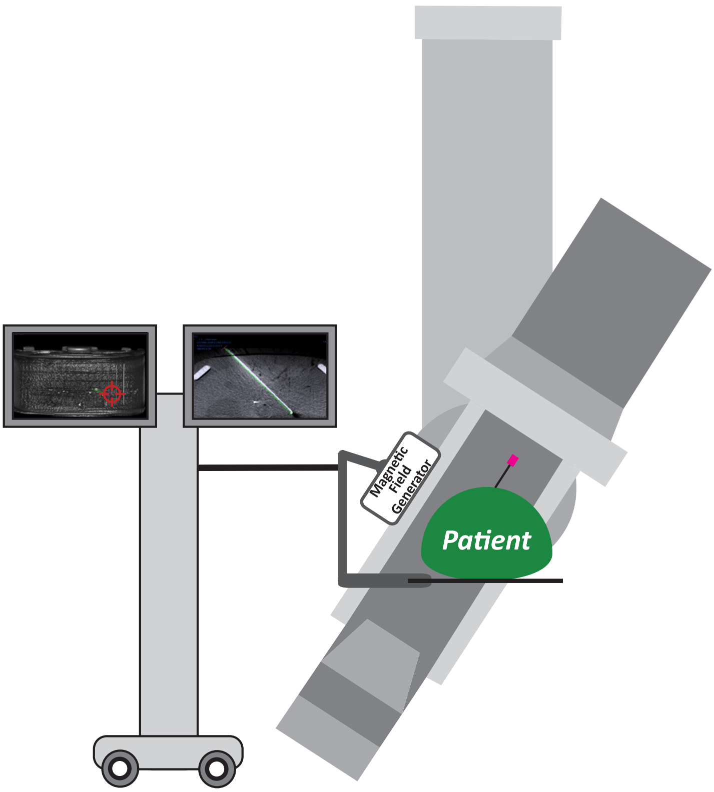


Figure 1.4: *Schematic presentation of an electromagnetic tracking system inside the angiography suite.*

Laser guidance

Laser guidance systems use a laser pointer to visualize the planned needle path. In most of these systems the skin entry point needs to be marked, which is used to calculate the angle for the needle path. By positioning the laser in the calculated angulation while the laser points at the skin entry point, the operator can insert the needle while keeping the needle hub illuminated by the laser beam. Commercially available devices are SimpliCT (NeoRad, Oslo, Norway) and 3D-LNS (Amedo, Bochum, Germany). SimpliCT needs a manual setup and angle calculation on the workstation of the scanner (19), while 3D-LNS is a motorized laser pointer on an arc shaped rail mounted in front of the gantry of the CT-scanner. By planning a needle path with their workstation, the laser unit automatically visualizes the planned needle path (20).

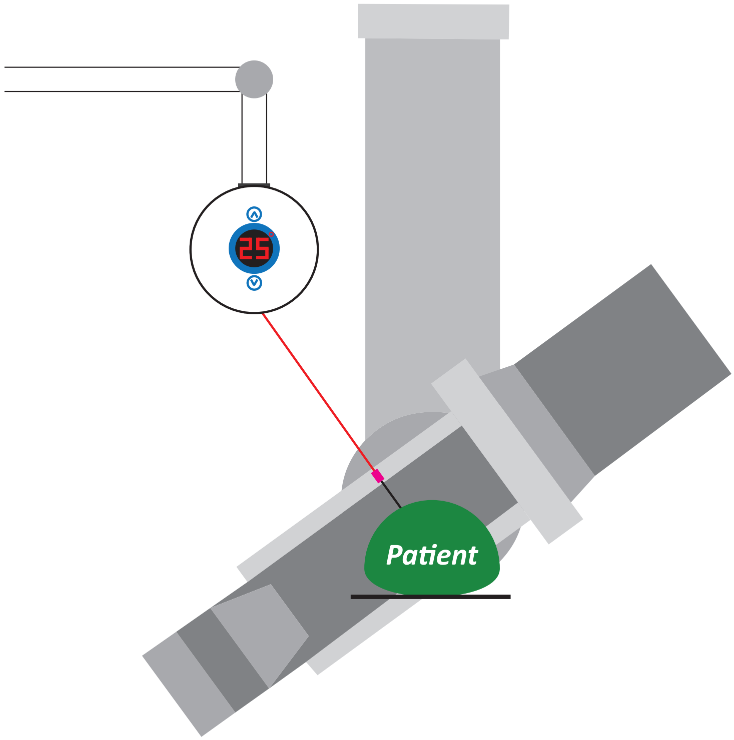


Figure 1.5: *Schematic presentation of a laser guidance system in the angiography suite.*

Needle holders

This category can be subdivided into systems that are patient-mounted and floor/table-mounted. The patient-mounted needle holders have the potential to reduce needle placement errors, since the moving target is often coherent to the motion of the patient skin. Mounting the system on the patient also means that these products needs to be low in weight and must not introduce artefacts during imaging. Two commercially available patient-mounted needle holders are Simplify (NeoRad, Oslo, Norway) and SeeStar (AprioMed, Uppsala, Sweden) (21). Both are sterile disposable needle holders and are primarily developed to hold the needle in place during imaging to avoid radiation exposure to the radiologist.

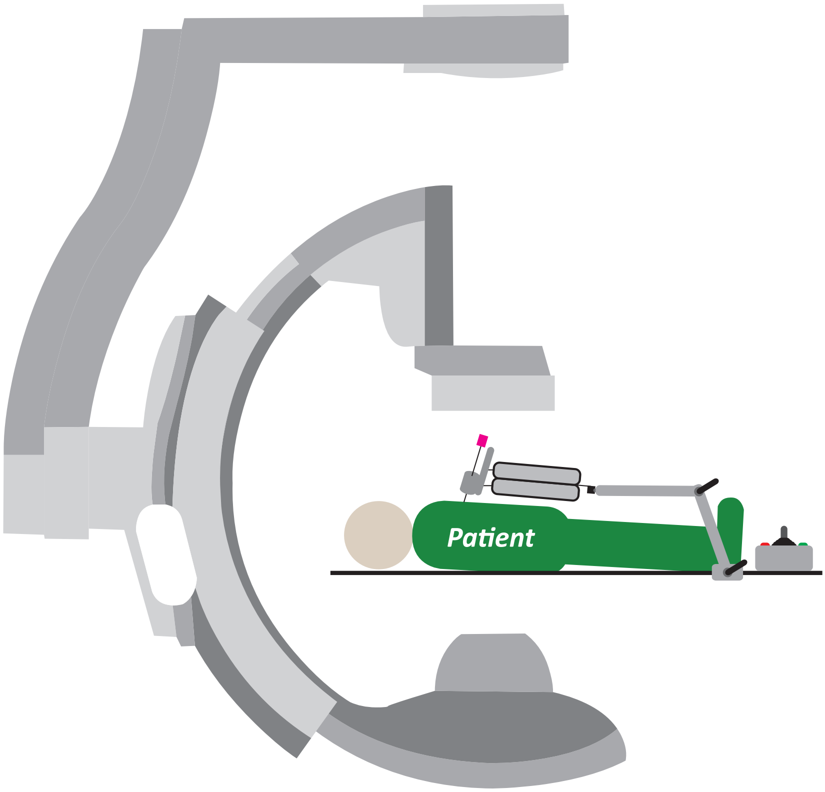


Figure 1.6: *Schematic presentation of a remote controlled needle holder in the angiography suite.*

Compared to the patient-mounted needle holders, the table/floor-mounted systems are heavier remote controlled needle holders using extra workstations for needle path planning. The commercially available needle holders for percutaneous needle interventions are iSYS (Interventional Systems, Kitzbühel, Austria), MAXIO (Perfint Healthcare, Chennai, India) and ROBIO (Perfint Healthcare). The iSYS-system requires a manual placement of the mechanical arm near the skin entry point. A remote controller is used to position the needle in the planned angulation and on the skin entry point while using fluoroscopy (22). The systems from Perfint Healthcare are robotic needle holders on wheels, positioned next to the CT-table on a calibrated docking station on the floor. The needle holder can automatically position the needle guide according to the planning. The parts holding the needle are disposable and the insertion of the needle is performed like the iSYS-system by the radiologist (23).

Table 1.1 shows the compatibility of the commercially available guidance devices to the type of imaging modality, the list price of the devices, the potential dose savings for patient and/or staff and the published results. The procedure times were not included in this table because of the different definitions for this term in the published articles. Many of the presented needle guidance devices were able to assist the radiologist in (cone-beam) CT-guided needle interventions (15-22, 24-32). A small selection of these devices proved to reduce the radiation exposure to patient and/or staff by limiting the number of control scans or preventing the use of CT-fluoroscopy (24, 28, 30). Only a small selection of these devices was used in a cone-beam CT-guidance setting and none of these articles described a comparison of the guidance device with the conventional freehand technique (17, 22). Figures 1.3-1.6 show the setup of the guidance techniques in a cone-bean CT guidance setting. Each technique has its strengths and weaknesses. For optical tracking techniques the direct line of sight between camera and markers is essential. This requirement might be challenging with the C-arm rotations during a needle intervention. Also the limited field of view of a cone-beam CT requires to carefully position the markers to limit unnecessary numbers of cone-beam CT scans (33). The direct line of sight might not be an issue for electromagnetic tracking, but the technique has been reported to encounter problems when metallic objects are in the presence of the skin entry point (34). In addition, the wired connection of the sensors and field generator to the workstation could limit the guidance. For both laser guidance and floor/table-mounted needle holders the C-arm rotations can be challenging. The laser guidance unit needs to be positioned outside the rotation area of the C-arm. One of the vendors has the option of a cross-hair laser inside the detector housing (35). Guidance by the laser pointer with the C-arm in progress view is in this case a limitation.

Guidance devices	CT compatibility	Cone-beam CT compatibility	List price	Dose saving potential for patient/staff
Tracking system				
CAS-ONE	Yes	No	D	Reduced radiation dose for patient and staff by reducing Dose Length Product (DLP) of the verification scans and fluoroscopy (24)
CT-Guide	Yes	No	C	N.S.
iGuide CAPPA	Yes	Yes	D	N.S.
CT-NAVIGATION	Yes	No	B-C	N.S.
Laser guidance				
SimpliCT	Yes	Yes, this thesis	B	This thesis
3D-LNS	Yes	No	C	Reduced the number of control scans and therefore reduced the radiation exposure for the patient (28)
Needle holders				
Simplify	Yes	Yes	A	This thesis
SeeStar	Yes	Yes	A	This thesis
iSYS	Yes	Yes	D	Potentially reduced radiation exposure for staff (22)
MAXIO	Yes	No	D	Reduced the number of control scans and therefore reduced the radiation exposure to the patient. Did require CT-fluoroscopy for needle repositioning (30)
ROBIO	Yes	No	C	N.S.

Table 1.1: *Commercially available guidance devices for CT- and/or cone-beam CT-guided needle interventions. List price categories are in numbers of €1000: Category A = 0-0.1; B= 10-50, C = 50-100 and D = 100-200.*

1

Published results: dose	Published results: accuracy	Reference
DLP: 3510 mGy•cm ± 887 vs. 4886 mGy•cm ± 1775* for freehand technique (CT guidance) [1]	2.2 mm ± 0.9 vs. 3.3 mm ± 1.2* for freehand technique (CT guidance) [1]	(15, 24)
DLP: 1543 mGy•cm (range 760-3777) (CT guidance) [1]	1.33 mm ± 0.72 (CT guidance) [2]	(16, 25)
Dose Area Product: 74 Gy•cm² (range 9-269) (cone-beam CT guidance) [1] Fluoroscopy time: 0.8 min (range 0.4-2) (cone-beam CT guidance)	5.4 mm ± 1.9 (cone-beam CT guidance) [1] 2.3 mm ± 0.9 (cone-beam CT guidance) [2]	(17, 26)
N.S.	3.7 mm (range 2-6.7) vs. 15 mm (range 10-20)* for freehand technique (CT guidance) [2]	(18)
DLP: 145 mGy•cm ± 50 vs. 206 mGy•cm ± 72* for freehand technique (CT guidance) [1]	This thesis	(19, 27)
	2.0 mm ± 1.2 vs. 3.5 mm± 1.7* for freehand technique (CT guidance) [2]	(20, 28)
This thesis	This thesis	
This thesis	This thesis	(21)
	2.3 mm ± 0.8 (CT guidance) [2] 1.1 mm (range 0-4.5) (cone-beam CT guidance) [2]	(22, 29)
DLP: 1382 mGy•cm ± 536 vs. 1611 mGy•cm ± 708* for freehand technique (CT guidance) [1] DLP: 2132 mGy•cm ± 626 vs. 4714 mGy•cm ± 1704* for freehand technique (CT guidance) [1]	2.2 mm (range 0-4) vs. 3.1 mm (range 0.2-6.2)* for freehand technique (CT guidance) [1]	(30, 31)
		(32)

N.S. means not studied, asterisk means significant difference compared to the freehand technique. 1 means patient study and 2 means phantom study.

OUTLINE OF THIS THESIS

If the number of needle interventions continues to increase as has been the case in the last decades, tools to assist the radiologist will play a bigger role in interventional radiology. For this reason, the research presented in the current thesis examines and evaluates the potential of needle guidance devices in assisting the radiologist during primarily cone-beam CT-guided needle interventions. To this end, the challenges in cone-beam CT-guided needle interventions are investigated and solutions are proposed.

The thesis starts with a selection of needle guidance devices, some compatible with cone-beam CT and some modified to be compatible. In a phantom study, the performance of these devices is compared to the freehand technique, the technique currently mostly used during these needle interventions (**chapter 2**). The effect of laser guidance on fluoroscopy time and radiation exposure to the operator was the reason to evaluate the guidance technique in a clinical setting. In a comparison with the freehand technique, laser guidance was used for cone-beam CT-guided biopsies to test the true potential (**chapter 3**). Another area in which a growing number of needle interventions are performed is thermal ablation therapy, a minimal invasive alternative for open surgery. Thermal ablation is a therapy for osteoid osteoma which occur mostly in children and young adults, a patient group very sensitive to radiation exposure. Based on outcomes of laser guidance in cone-beam CT-guided biopsies, in **chapter 4**, laser guidance is added to RF ablation of osteoid osteoma using cone-beam CT-guidance to evaluate if laser guidance could play a role in minimizing fluoroscopy, reducing the procedure times and maximizing the accuracy of the puncture.

In the studies presented in **chapters 2-4**, primarily experienced radiologists used laser guidance in combination with cone-beam CT; however, this tool could also be of help to the inexperienced radiologist/fellow. As the main stay of biopsies are currently performed using CT, in **chapter 5** the potential of laser guidance as a learning aid to shorten the training and learning curve for radiology residents is examined in CT-guided needle interventions.

The success of image-guided needle interventions is not determined by clinical skills and guidance devices alone. Patient and respiratory motion present one of the major clinical challenges, especially for small targets in the thorax and upper abdomen. The issue of patient movement can partly be solved by using vacuum mattresses, which fixates the patient to some extent. Dealing with respiratory motion is more difficult. First of all, a cone-beam CT is acquired in 5 seconds for a fast low-dose scan; however, a higher resolution scan requires 10 seconds. Especially for small targets in the upper abdomen or thorax, breathing artefacts in the images should be prevented. One option is a steady breath-hold during the scans and performing the procedure during a comparable breath-hold. To ensure the same breath-hold during imaging and the procedure, a new technique for a breath-hold monitor is proposed in **chapter 6**.

Finally, the **chapter 7** provides a general discussion and future perspective for cone-beam CT-guided needle interventions.

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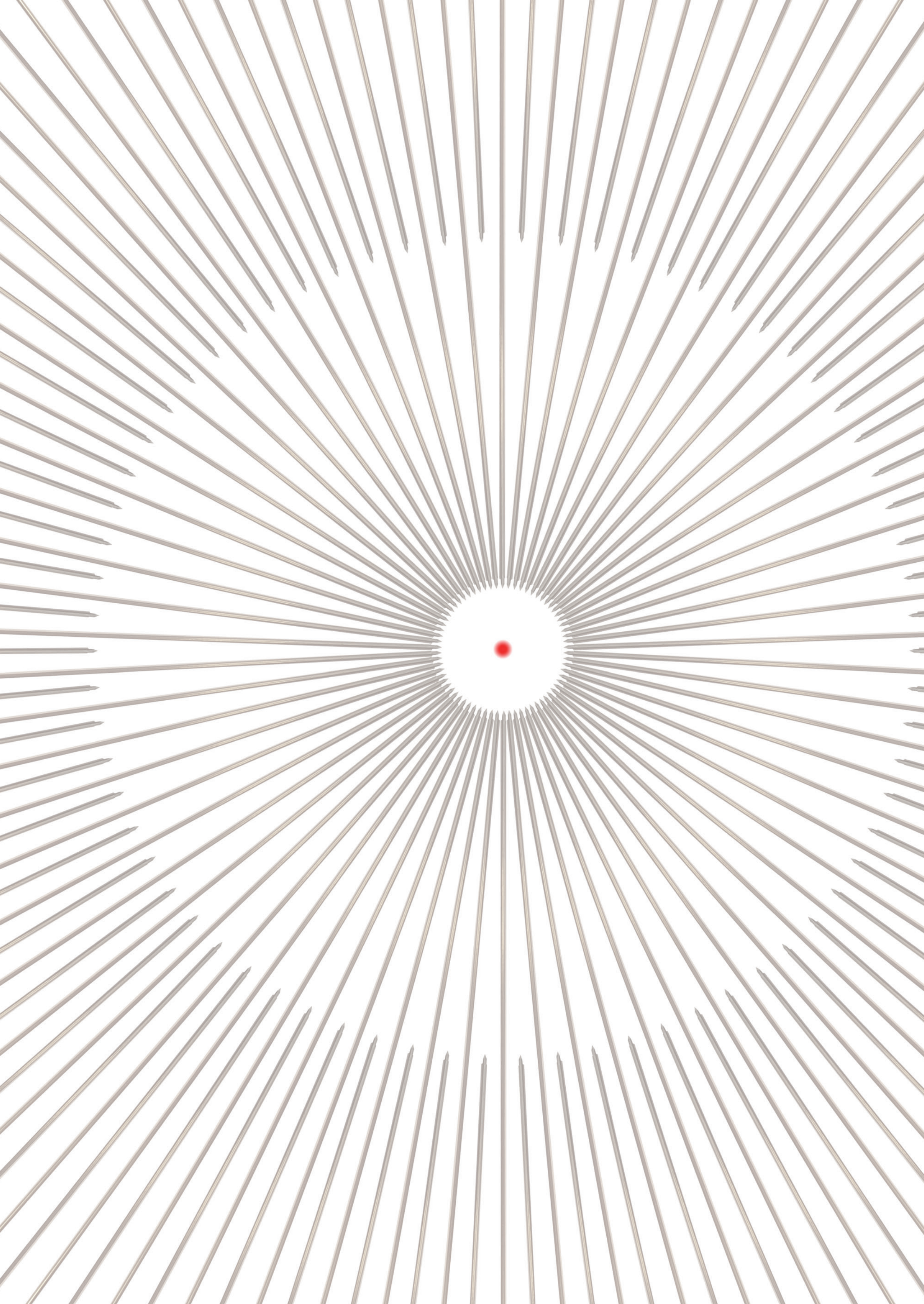

2

Assessment of needle guidance devices for CBCT-guided needle interventions

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ABSTRACT

Purpose

To assess whether the use of needle guidance devices can reduce fluoroscopy time and operator hand dose during cone-beam computed tomography-guided needle interventions.

Materials and Methods

The freehand technique was compared with techniques employing two distinct needle holders and a ceiling-mounted laser guidance technique. Laser guidance was used either alone or in combination with needle holders. Four interventional radiologists were instructed to reach predetermined targets in an abdominal phantom using these techniques. Each operator used all six techniques three times. Fluoroscopy time, procedure time, operator hand dose, and needle tip deviation were obtained for all simulated needle interventions. All data are presented as median (ranges).

Results

All procedures were successfully completed within 2-4 minutes, resulting in a deviation from target of 0.8 mm (0-4.7). In freehand procedures, the fluoroscopy time to reach the target was 50 seconds (31-98 s). Laser guidance, used alone or in combination with needle holders, reduced fluoroscopy time to 31 seconds (14-68 s) ($P < 0.02$). The operator hand dose in freehand procedures was 275 μSv (20-603 μSv). Laser guidance alone or in combination with needle holders resulted in a reduction of the hand dose to < 36 μSv (5-82 μSv) per procedure ($P < 0.001$). There were no statistically significant effects on hand dose levels or fluoroscopy time when the needle holders were employed alone.

Conclusion

Compared with the freehand technique, all three tested needle guidance devices performed with equivalent efficiency in terms of accuracy and procedure time. Only the addition of laser guidance was found to reduce both fluoroscopy time and operator hand dose.

INTRODUCTION

The development of cone-beam computed tomography (CT) within a C-arm angiography system has led to the development of an image guidance technique for needle interventions in the angiography suite (1, 2). Several authors have described the use of cone-beam CT in procedures involving targeted percutaneous needle interventions (3-11). During these procedures, a cone-beam CT volume is used for needle path planning, while fluoroscopy and the rotational capabilities of the C-arm provide real-time feedback during needle placement and advancement (2, 12). Compared with conventional CT-guided needle interventions, the use of cone-beam CT guidance has been reported to improve patient access (12), and to reduce radiation exposure to the patient (4).

One important limitation of cone-beam CT image guidance is that using two-dimensional fluoroscopy feedback to monitor needle advancement, the operator lacks either depth or angular information of the actual needle path, depending on the viewing angle. To monitor both depth and angular information, the operator needs to switch between entry point view–an overlay of entry and target point in a bull's-eye fashion–and progress view–perpendicular to the entry point view. If necessary, corrections to the actual needle path angle can be made in the entry point view (2, 3, 13). In our experience, these corrective needle manipulations frequently result in placement of the operator's hand inside the primary radiation beam.

For CT-guided needle interventions, the use of needle holders has been suggested to increase accuracy and aid in decreasing the number of needle manipulations and control scans, saving time and limiting radiation dose to the patient (14). Although cone-beam CT-guided needle placements using needle holders have been described (11, 13), the effect of needle holders on these parameters in cone-beam CT-guided procedures have not been reported. The purpose of this study was to assess whether the use of needle guidance devices could also aid in reducing the number of manipulations in cone-beam CT-guided needle interventions, reducing fluoroscopy time and operator hand dose. We further assessed whether these devices could aid in optimizing these procedures in terms of procedure time and accuracy.

MATERIALS AND METHODS

Procedure

Needle interventions were performed on an abdominal phantom (Model 057 Triple Modality 3D Abdominal Phantom; CIRS, Norfolk, USA) using an 18-gauge needle. Four radiopaque 2.3-mm diameter spheres (CT-SPOTS; Beekley, Bristol, USA) placed inside the phantom were used as targets (Figure 2.1). These small high density targets were chosen to determine accurately the deviation from needle tip to target.

Figure 2.1: *Cone-beam CT slice of the used phantom. The four radiopaque targets were positioned at a depth of between 9cm and 13cm inside the phantom.*

Cone-beam CT-guided needle interventions were performed using a C-arm angiography system (Allura Xper FD20 ;Philips Healthcare, Best, The Netherlands). Cone-beam CT volumes were acquired and used to plan a needle path between a randomly selected skin entry point and one of the four targets using the XperGuide software (Philips Healthcare) (2). Axial needle paths with maximum angulations of 45 degrees were used because this is currently the maximum angle for the laser guidance device. Care was taken not to plan paths along previously followed trajectories to prevent bias caused by previously deformed phantom material. Cone-beam CT-guided needle interventions involved locating and marking the skin entry point on the phantom and placing the needle in the planned angle under fluoroscopy guidance with the C-arm in entry point view. In the entry point view, the overlay of entry and target point and the cone-beam CT volume are superimposed on real-time fluoroscopy. The operator visualized the advancing needle in the progress view, perpendicular to the entry point view, along the needle shaft and with the planned path as well as cone-beam CT superimposed on real-time fluoroscopy (2, 12).The needle intervention was completed when the needle was placed onto the target according to the operator. A second cone-beam CT scan was obtained for accuracy measurements.

Needle guidance devices

In this study, cone-beam CT-guided freehand needle placements were compared with interventions employing commercially available needle guidance devices. A ceiling-mounted laser guidance technique and two distinct needle holders were used.

The needle holders used were the SeeStar (AprioMed, Uppsala, Sweden) and Simplify (NeoRad, Oslo, Norway) (Figure 2.2). Both needle holders allowed rotation and angulation of the needle, while maintaining it in a fixed angle during advancement. The metallic needle guide of the SeeStar could be used to position the needle holder because it was visible on fluoroscopy (14, 15). A practical advantage of Simplify was that it could be detached without removing the needle.

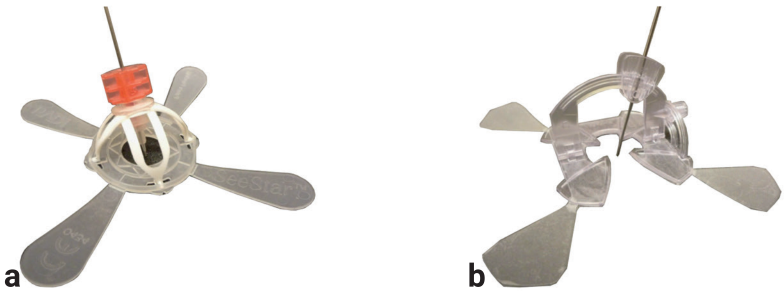

Figure 2.2: *The two different types of needle holders used for assisting the operator in needle placement. (**a**) SeeStar (**b**) Simplify.*

The laser guidance unit (SimpliCT; NeoRad) acted as a laser pointing device with the possibility to visualize the planned needle path for the operator (16-18). The ceiling-mounted version of the device used in this study could be used to maximum angulations of 45 degrees in the axial and craniocaudal direction. The guiding laser suspension inside the unit was self-leveling, and the unit contained an additional plane laser to align it with the operating table. Using information obtained from the vendor of the angiography system, the angles of the C-arm position in the entry point view were recalculated to yield the planned needle path angles in three-dimensional views. These angles were subsequently fed into the laser guidance unit. With the C-arm positioned in the progress view, the laser unit was positioned such that the guiding laser aimed at the previously marked skin entry point and the plane laser beam was in alignment with the operating table (Figure 2.3). The freehand technique was compared with procedures performed with the aid of SeeStar, Simplify, and SimpliCT alone and with procedures employing SimpliCT-SeeStar and SimpliCT-Simplify combinations. The simulated needle interventions were performed by four interventional radiologists. Three interventional radiologists had 3-5 years of experience in cone-beam CT-guided needle interventions, and one (a fellow) had 1 year of experience. Because the operators had no experience in using the needle guidance devices, all operators performed one needle intervention with each guidance device as training. For this phantom study, all four operators performed three needle placements per technique to verify reproducibility and facilitate interoperator analysis.

Outcome measures

Fluoroscopy time, procedure time, radiation exposure to the hand of the operator, and accuracy were recorded.

Fluoroscopy time was obtained from the angiography system software and was defined as the time in seconds of real-time fluoroscopy necessary for locating the skin entry point, placing and aligning of the needle, and advancing the needle onto the target.

Procedure time of the simulated intervention was defined as the time necessary to place the needle onto the target, including the setup time for the needle guidance devices but excluding the time required for placing the phantom on the table, acquiring both cone-beam CT scans and needle path planning. Procedure time was measured by one author (M.W.K.) using a stopwatch.

2

Figure 2.3: *Schematic presentation of the laser guidance setup. The guiding laser of SimpliCT is aimed along a planned needle path of 30 degrees in the axial direction (straight line), while the plane laser is aligned to the operating table (dashed line). The C-arm is positioned in progress view.*

Radiation exposure to the hand manipulating the needle was measured in microsieverts (μSv) using a dosimeter with a small-tip sensor, (EDD-30; Unfors Instruments, Billdal, Sweden). The sensor of the dosimeter was placed on the back of the hand manipulating the needle between the thumb and index finger.

Accuracy, defined as the distance between target edge and needle tip in the control cone-beam CT scan, was measured on the angiography system's dedicated three-dimensional workstation (XtraVision; Philips Healthcare) and assessed to monitor the performance of the operators.

Statistical analysis

All statistical analyses were conducted in SPSS (version 16.0.01; SPSS Inc., Chicago, USA). All results are represented as medians with corresponding ranges. Differences between the freehand technique and techniques using needle guidance devices were analyzed using the Mann-Whitney U test. Differences in performances between operators were analyzed for all techniques using the Kruskal-Wallis test. Differences were considered statistically significant for $P < 0.05$.

RESULTS

In needle interventions using the freehand technique, median fluoroscopy time needed to reach the target was 50 seconds (31-98 s). The median fluoroscopy time for laser-guided needle interventions was 31 seconds (14-55 s) for SimpliCT, 30 seconds (15-55 s) for the SimpliCT-SeeStar combination, and 29 seconds (16-68 s) for the SimpliCT-Simplify combination. Compared with the freehand technique, significantly shorter fluoroscopy times were achieved using SimpliCT (P = 0.004) and the combinations SimpliCT-SeeStar (P = 0.001) and SimpliCT-Simplify (P = 0.018) (Figure 2.4). Both needle holders alone did not result in a statistically significant difference in outcomes compared with the freehand technique: SeeStar, 67 seconds (40-95 s; P = 0.193); Simplify 59 seconds (30-138 s; P = 0.898).

Except for the procedures using the SeeStar (2.8 min [1.6-5.1 min]; P = 0.098), the procedure time for the freehand technique (1.9 min [0.8-3.6 min]) was statistically significantly shorter compared with all other guidance devices. Procedure times were 3.1 minutes (1.7-5.8 min;

P = 0.028) using Simplify and 2.9 minutes (2.2-6.1 min; *P* = 0.007) for SimpliCT; for the combinations SimpliCT-SeeStar and SimpliCT-Simplify, procedure times were 3.6 minutes (1.3-5.5 min; *P* = 0.005) and 3.5 minutes (2.0-5.5 min; *P* = 0.001), respectively.

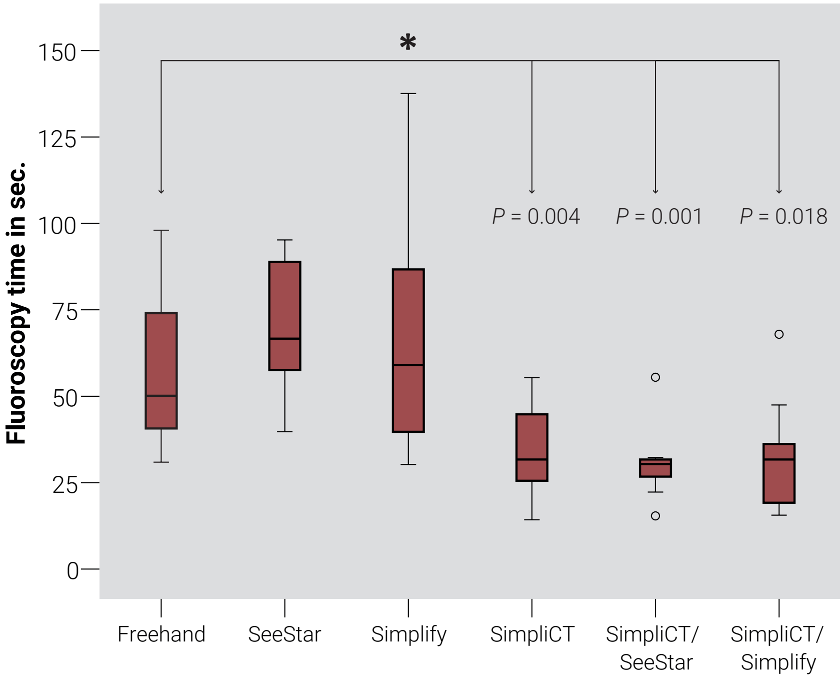

Figure 2.4: *Box plot representing the fluoroscopy times in seconds required to guide the needle onto the target per needle guidance device. The asterisk represents a statistically significant difference between the freehand technique and laser-guided procedures.*

The measured operator hand dose for the freehand technique was 275 μSv (20-603 μSv). SimpliCT-guided needle interventions resulted in a significantly reduced operator hand dose of 33 μSv (8-82 μSv; *P* = 0.001). Similar results were obtained for SimpliCT in combination with the needle holders (SimpliCT-SeeStar, 36 μSv [8-82 μSv]; SimpliCT-Simplify, 32 μSv [5-79 μSv]; both combinations *P* = 0.001) (Figure 2.5). All procedures with SimpliCT showed only a very small variation in hand dose measurements. Both needle holders alone showed no statistically significant difference compared with the freehand procedure: SeeStar, 298 μSv (80-876 μSv; *P* = 0.478); Simplify, 167 μSv (42-464 μSv; *P* = 0.699).

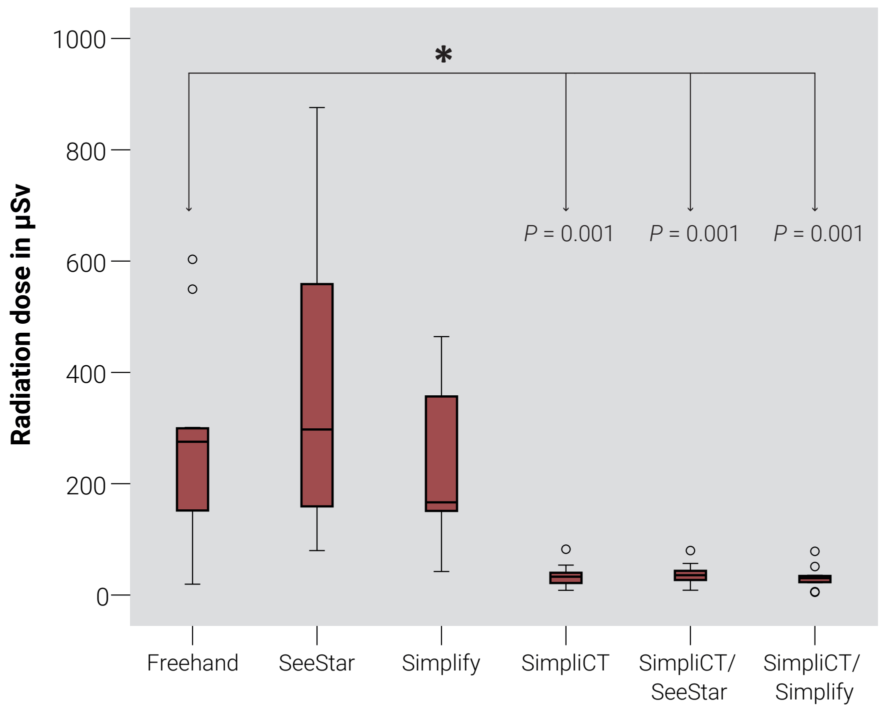

Figure 2.5: *Box plot showing the measured radiation hand dose per needle guidance technique. The asterisk represents statistically significant lower (P = 0.001) hand dose for laser-guided procedures compared with the freehand technique.*

The measured deviation from the target for the freehand technique was 1.2 mm (0.1-3.5 mm). There were no significant differences in accuracy between procedures using any of the needle guidance devices compared with the freehand technique. Seestar-guided needle interventions resulted in a deviation of 0.4 mm (0-1.5 mm; P = 0.090); Simplify, 0.9 mm (0.1-4.7 mm; P = 0.961); SimpliCT, 0.2 mm (0-1.8 mm; P = 0.075); SimpliCT-SeeStar, 0.2 mm (0-4.1 mm; P = 0.091); and SimpliCT-Simplify, 0.3 mm (0-1.7 mm; P = 0.106).

Finally, the data did not show any statistically significant difference in interoperator performance.

DISCUSSION

The most essential findings of this phantom study are that adding laser guidance to cone-beam CT-guided needle interventions significantly reduces fluoroscopy time and operator hand dose. Compared with freehand techniques, laser guidance prolongs procedure times by only a few minutes, a difference that likely would go unnoticed in clinical practice.

Hand doses during interventional radiology procedures can be high; dose levels up to several millisievert per procedure, consistent with exposure of the hand to the primary x-ray beam, have been reported (19, 20). Sterile radiation-attenuating surgical gloves are commercially available. These gloves can provide significant protection from scatter radiation but provide only minimal protection when hands are placed in the primary x-ray beam (21-23). The reduction in operator hand dose by employing laser guidance is attributable to the more efficient placement of the needle and the reduced number of corrective needle manipulations in the entry point view, effectively preventing direct exposure of the hands to the primary beam leaving scatter radiation as the predominant contribution to the operator's hand dose.

For CT-guided needle interventions, the use of the SeeStar needle holder has been suggested to increase accuracy and aid in decreasing the number of needle manipulations and control scans, saving time as well as radiation exposure to the patient (14). The authors attributed these effects mainly to the metallic needle guide creating a streak artefact pointing at the target in the CT images, indicating the needle path. In our simulated C-arm cone-beam CT-guided interventions, the needle holders were employed only after the cone-beam CT scan was made and the streak artifact did not appear in fluoroscopy, so the effect on accuracy was not apparent. In addition, the design of the study was such that all techniques, including freehand, involved simultaneous visualization of the advancing needle, the planned needle path, and the cone-beam CT volume superimposed on real-time fluoroscopy–essentially rendering all techniques equally accurate. In our simulated cone-beam CT-guided interventions, the use of needle holders did not show an effect on the number of corrective manipulations compared with freehand, as evidenced by similar fluoroscopy times and operator hand dose levels. Similar to the freehand technique, when employing the needle holders, the placement of the needle still required frequent adjustments of the needle angle in the entry point view. Based on our experience, the added value of the needle holders in cone-beam CT-guided percutaneous procedures is in the physical support they provide while advancing the needle.

Schultz et al (24) recently described a phantom study in which the use of a table-mounted, remote-controlled, small robotic device capable of holding and guiding needles in aiding needle interventions was investigated. These authors indicated that accuracies < 5 mm were feasible when using this device and that no direct exposure of the physician's hands to the primary radiation occurred owing to remote control. Compared with laser guidance as described in this study, one important drawback of using such automated guidance devices is that the needle holder is positioned in the primary beam during initial alignment. This positioning may increase radiation exposure to the patient. In addition, because no table mounting is involved, setting up laser guidance in a sterile environment in our daily clinical routine is completed within minutes. This is significantly faster than the reported ≥ 10 minutes of setup time required for the robot (24).

There are several limitations to this study. For practical reasons, the operators were asked to simulate three needle interventions for all six techniques. Although the resulting data did not provide evidence for differences in interoperator performance, the dataset may be too small to address questions relating to operator experience or learning curves. Second, at the present time, cone-beam CT guidance cannot compensate for target motion after the needle path planning is done. In case the patient moves with the needle already inserted, laser guidance could help in getting the physician back on track, but more often patient movement would require a new cone-beam CT scan and planning procedure to be performed (11,12). When frequent motion compensations are required in clinical practice, the reduction of fluoroscopy time by using laser guidance would not reach the same level as presented in this study. However, even in these cases, laser guidance would prevent exposure of the operator's hands to the primary x-ray beam.

The freedom of movement of the current version of the laser guidance setup limits its applicability to guiding needle paths within the range of 45 degrees, in all directions from the vertical axis. The design of the current study further involved simulated, in plane trajectories only. However, the combination of laser guidance and cone-beam CT-guided needle interventions can be applied just as easily to double oblique trajectories.

In conclusion, adding laser guidance to cone-beam CT-guided needle interventions provides visual feedback that effectively prevents exposure of the hands of the operator to the primary radiation beam. The use of laser guidance maintains tactile feedback and facilitates accurate needle placements within essentially the same time as freehand procedures.

The extent to which laser guidance in cone-beam CT-guided needle interventions can aid in reducing fluoroscopy time and patient exposure in clinical practice is currently under investigation.

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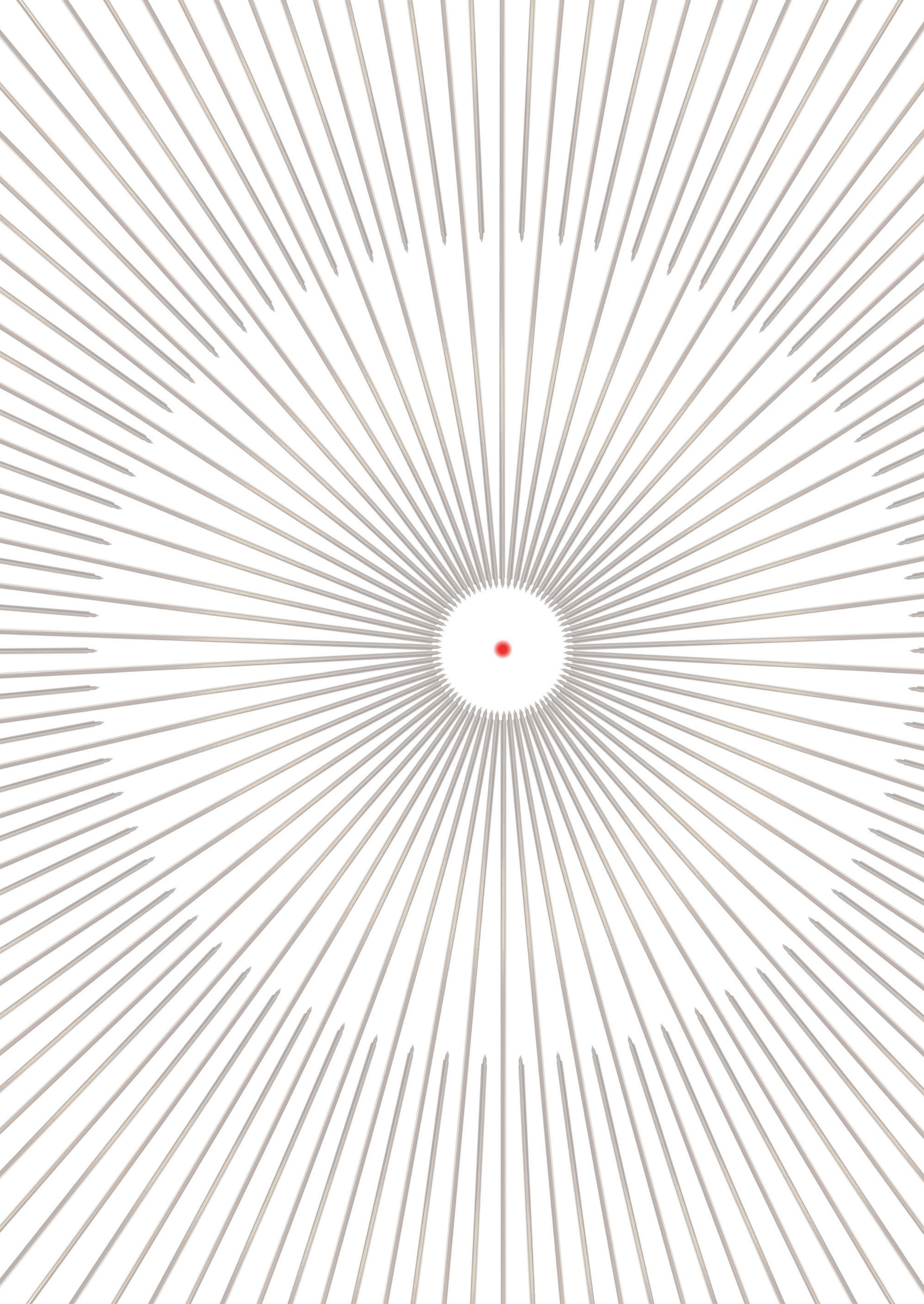

3

Laser guidance for CBCT-guided biopsies

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ABSTRACT

Purpose

When using laser guidance for cone-beam computed tomography (CT) -guided needle interventions, planned needle paths are visualized to the operator without the need to switch between entry- and progress view during needle placement. The current study assesses the effect of laser guidance during cone-beam CT-guided biopsies on fluoroscopy and procedure times.

Materials and Methods

Prospective data from 15 cone-beam CT-guided biopsies of 8-65 mm thoracic and abdominal lesions assisted by a ceiling mounted laser guidance technique were compared to retrospective data of 36 performed cone-beam CT-guided biopsies of lesions > 20 mm using the freehand technique. Fluoroscopy time, procedure time and number of cone-beam CT scans were recorded. All data are presented as median (ranges).

Results

For biopsies using the freehand technique, more fluoroscopy time was necessary to guide the needle onto the target, 165 seconds (83-333 s) compared to 87 seconds (44-190 s) for laser guidance ($P < 0.001$). Procedure times were shorter for freehand-guided biopsies, 24 minutes versus 30 minutes for laser guidance ($P < 0.001$).

Conclusion

The use of laser guidance during cone-beam CT-guided biopsies significantly reduces fluoroscopy time.

INTRODUCTION

Transferring percutaneous needle interventions from a conventional CT-suite to an interventional suite that uses C-arm cone-beam computed tomography (CT) as image guidance technique has several advantages. Firstly, removing the rather time consuming interventional procedures from the conventional CT-suite increases the patient throughput for diagnostic computed tomography (CT) scans (1). Secondly, the use of cone-beam CT guidance has been reported to improve patient access due to absence of a gantry (2). Thirdly, cone-beam CT offers the advantages of availability of planning software for double oblique projections and the capability to combine cone-beam CT with a stereotactic navigation device giving the operator the possibility of planning the most optimal needle path from skin entry to target (3, 4). Lastly, cone-beam CT has been reported to reduce radiation exposure to the patient compared to conventional CT-guided needle interventions (5).

Real-time feedback on the needle position during cone-beam CT-guided needle interventions is provided by fluoroscopy. An earlier phantom study showed that during cone-beam CT-guided needle interventions manipulations of the needle are frequently accompanied by placement of the operator's hand inside the primary radiation beam (6). The latter should be avoided whenever possible since hand dose levels can be up to several millisieverts per procedure (7, 8). By adding laser guidance to the cone-beam CT guidance, radiation exposure was shown to be reduced. The more efficient placement of the needle and fewer corrective needle manipulations minimized direct exposure of the hands to the primary beam and left scatter radiation as the predominant contribution to the hand dose (6).

This study assesses the effect of laser guidance during cone-beam CT-guided biopsies on fluoroscopy and procedure times.

MATERIALS AND METHODS

Cone-beam CT guidance

The cone-beam CT-system in our department is the Allura Xper FD-20 angiosystem (Philips Medical Systems, Best, The Netherlands). In the acquired cone-beam CT-volume a target is defined and a needle path is planned by the operator. Thereafter the C-arm is used to guide the needle in real-time along the planned needle path onto the target using fluoroscopy. Two

C-arm geometry positions are mainly used to guide a needle: the entry point view, which is an overlay of entry and target point in a bull's eye fashion, and the progress view, which is perpendicular to entry point view (9).

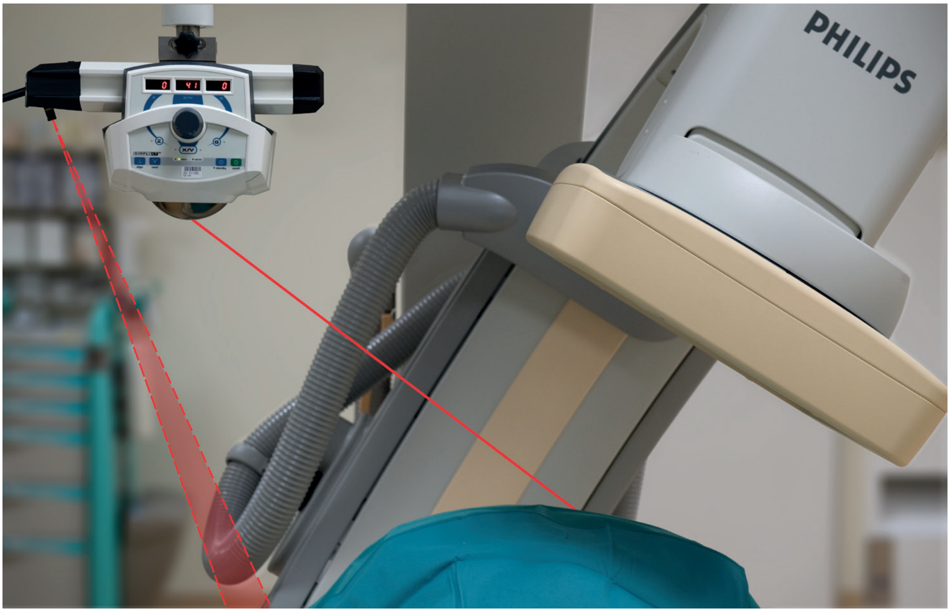


Figure 3.1: *Schematic presentation of the laser guidance setup. The guiding laser of SimpliCT (NeoRad AS, Oslo, Norway) is aimed along a planned needle path of 41 degrees in the axial direction (straight line), while the plane laser (dashed lines) is aligned to the operating table. The C-arm is positioned in progress view.*

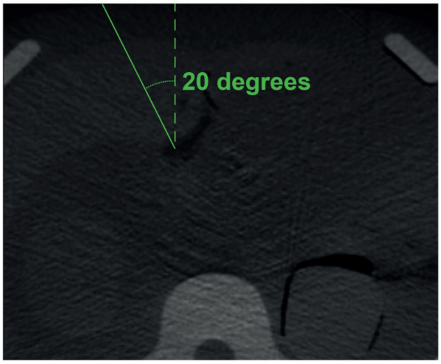
Laser Guidance System

SimpliCT (NeoRad AS, Oslo, Norway) is a laser-based guidance device for CT-guided percutaneous interventions. The laser guidance acts as a laser pointing device to visualize the planned needle path (possible to 45 degrees in the transversal and sagittal planes) for the operator. For this study SimpliCT was integrated into the angiosuite. The battery driven laser pointer unit was suspended on a short rail from a Mavig Portegra2 arm. A plane laser was attached to this rail for perpendicular alignment of the laser unit to the C-arm system, using the operating table for horizontal reference alignment (Figure 3.1).

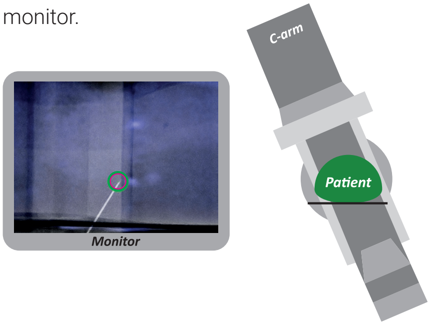
Procedure

After acquiring the cone-beam CT-volume of the designated patient area the needle path was planned. The angles for the planned needle path, visible in the planning software (XtraVision; Philips Healthcare, Best, The Netherlands), were fed into the laser guidance system. With the C-arm in entry point view, the skin entry point on the patient was found using fluoroscopy and marked. After the C-arm was positioned in progress view, the laser unit was positioned such that the guiding laser was aimed at the marked skin entry point while the plane laser beam was in alignment with the operating table (Figure 3.1). With the pointing laser above the skin entry point, the needle was progressed by keeping the needle hub in the laser beam. Fluoroscopy was used to check the needle depth during advancement. These steps are visualized in Figure 3.2.

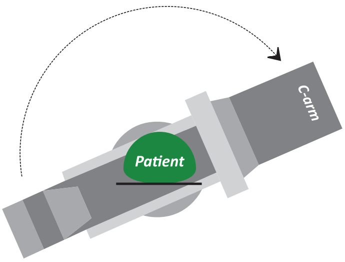
Step 1
Plan a needle path
In this example a needle path of 20 degrees



Step 2
Find and mark the entry point using fluoroscopy
- Place the C-arm in the entry point view
- Use needle and fluoroscopy to find the skin entry point visualized as a bulls-eye on the monitor.

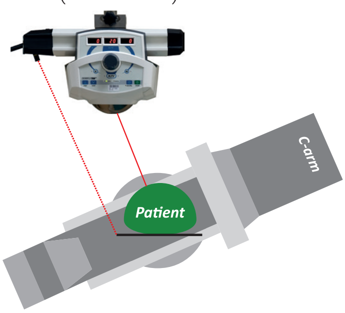


Step 3
Rotate C-arm in progress view



Step 4
Put angle of planned needle path in laser-unit

Step 5
Position laser-unit such that the guiding laser aims at the skin entry point (straight line) and the plane laser is in alignment with the operating table (dashed line)



Step 6
Progress needle while keeping needle hub in laserbeam until target is reached according to fluoroscopy images on the monitor

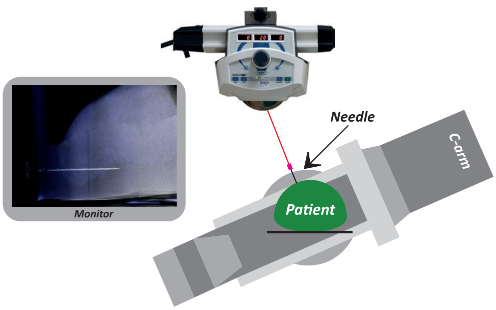


Figure 3.2: *A detailed visualization of the steps during laser guidance in cone-beam CT-guided biopsies*

Patients

A group of 15 patients with an indication for a cone-beam CT-guided biopsy were prospectively included in this study and underwent a cone-beam CT-guided intervention with laser guidance. There were no restrictions in terms of target location or lesion size. Patients had to be able to lie reasonably still and comply with breath-hold commands. All procedures were performed by one interventional radiologist with 4 years of cone-beam CT-guided needle interventions experience (M.J.L.S). Of the 15 biopsies with laser guidance, 7 were thoracic biopsies and 8 were abdominal biopsies. The prospective acquired data were compared to retrospective acquired cone-beam CT-guided freehand positioned biopsies. To test the hypothesis that laser guidance also reduces fluoroscopy times in a clinical setting, we chose to assess the minimal gain using laser guidance by selecting only relatively easy procedures from the retrospective freehand biopsies. Selection criteria for these biopsies were set at a target size larger than 20 mm in diameter and a procedure time shorter than 35 minutes. From the total of 82 biopsies, 36 biopsies (16 thoracic and 20 abdominal) met these criteria. All procedures were performed by two interventional radiologists (M.J.L.S. and S.J.B.).

Patient characteristics of both groups are provided in Table 3.1. The study was exempted for approval by the institutional review board. The laser system is commercially available and is used in standard practice for biopsy procedures.

Outcome Measures

Fluoroscopy time, procedure time, and the number of cone-beam CT scans were obtained.

Fluoroscopy time was defined as the time in seconds of real-time image guidance necessary for placing the needle onto target. These data were extracted from the angiography system software.

Procedure time was defined as the time from the first cone-beam CT until the last taken biopsy.

Technical success was defined as the needle tip positioned directly in front of the target or in the target and along the planned needle path. This was measured using the control cone-beam CT images before a biopsy was taken.

	Laser guidance	CBCT guidance	*P*-value
Number patients	15	36	
Age (yr)	65 (48-82)	66 (23-85)	$P = 0.963$
Biopsy region (abdominal/thoracic)	8/7	20/16	
Target size min diameter (mm)	15 (8-60)	35.5 (20-93)	$P < 0.001$
Target size max diameter (mm)	20 (10-65)	43 (22-124)	$P < 0.001$
Fluoroscopy (s)	87 (44-190)	165 (83-333)	$P < 0.001$
Procedure time (min)	30 (20-45)	23.5 (3-35)	$P < 0.001$
No. CBCT scans	2 (2-4)	2 (2-4)	$P = 1$

Table 3.1: *Patient and biopsy characteristics*

Statistical Analysis

All statistical analyses were conducted in SPSS (version 20.0.0; SPSS Inc., Chicago, USA). All results are represented as medians with corresponding ranges and analyzed using the Mann-Whitney U test. Differences were considered statistically significant for $P < 0.05$.

RESULTS

Technical success was achieved in 100% of the procedures for both laser guided and the freehand technique.

In the selected freehand biopsies, median fluoroscopy time required for reaching the target was 165 seconds (83-333 s). The median fluoroscopy time for laser-guided biopsies was 87 seconds (44-190 s). Comparing these results the fluoroscopy times were significantly lower ($P < 0.001$) (Figure 3.3) in the laser-guided biopsy group.

No significant differences were found in the number of cone-beam CT-scans per procedure. Both techniques used a median of 2 cone-beam CT-scans (2-4) per procedure.

When comparing procedure times, more time was required for the laser guided biopsies (30 minutes) than the selected freehand biopsies (24 minutes) ($P = 0.001$).

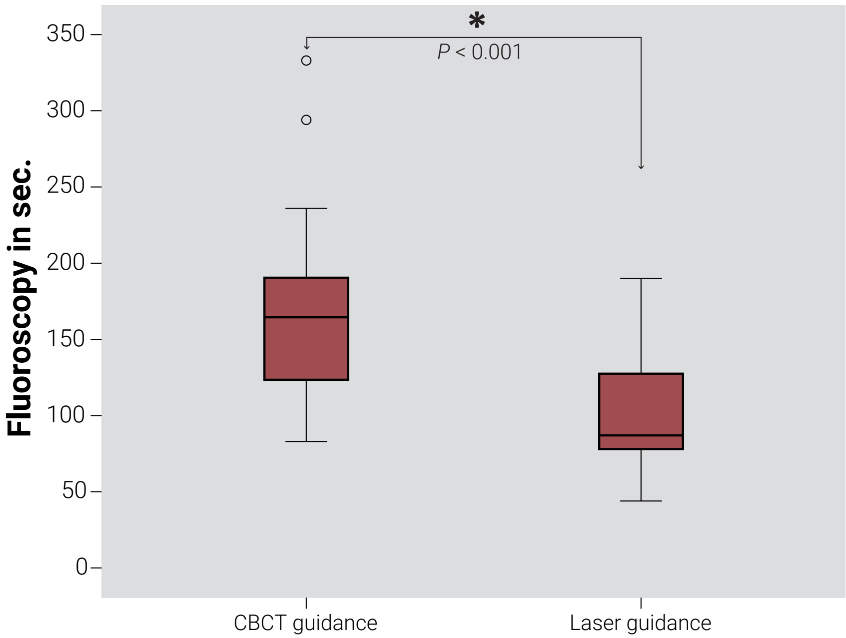


Figure 3.3: *Box plot depicting the fluoroscopy times in seconds required guiding the needle onto the target. Fluoroscopy times for laser guided biopsies were significantly lower (P < 0.001).*

DISCUSSION

The important finding of this study is that by adding laser guidance to cone-beam CT-guided biopsies there is a significant reduction in fluoroscopy time. Decreasing the fluoroscopy time directly influences the radiation exposure to both the patient and staff. The percentage of fluoroscopy time reduction from freehand to laser guidance is similar to the reduction seen in a laboratory setting using a phantom (6).

The reduction in fluoroscopy time by employing laser guidance is attributable to the visualization of the planned needle path, leading to a more efficient placement of the needle and a reduced number of corrective needle manipulations. Braak et al. (5) and Tselikas et al. (10) found a relatively high contribution of fluoroscopy in the total effective dose to the patient for cone-beam CT-guided needle interventions (35%-45%). In this setting the clinical operator may therefore also be potentially exposed to high levels of radiation during cone-beam CT-guided needle procedures. Keeping the fluoroscopy time as low as possible should therefore be a target for cone-beam CT-guided procedures.

Alternative strategies aiming to reduce fluoroscopy times have recently been reported. Only a few have been developed specifically for cone-beam CT-guided needle interventions (11-14). These robotic and electro-magnetic navigational devices can visualize the needle position in the scanned volume in real-time but require additional installment times for each procedure. Recently, Ritter et al reported the use of a crosshair laser integrated into the detector housing of an angiography system as an aid to reduce fluoroscopy time in cone-beam CT guided procedures. The crosshair laser was used to visualize the needle entry point on the skin of the patient on the basis of the planned path with the C-arm in entry point view (15, 16). In progress view, however, with the C-arm perpendicular to the planned needle path, the crosshair laser is unable to help the operator in maintaining the correct angle of the needle during progression. The effect on fluoroscopy time using laser guidance was not assessed in the Ritter study.

In the current study there were no differences in cone-beam CT-scans between the freehand technique and laser guidance. By giving breathing instructions and instructing the patient not to move during the procedure we were able to minimize the number of cone-beam CT-scans, which is a standard protocol for both techniques.

There are several limitations to the current study. First of all, prospective laser guidance data was compared to retrospective data. All performed cone-beam CT-guided needle interventions were collected in a database since the installation of our cone-beam CT-system. To be able to analyze laser guidance performance in an efficient manner this study was therefore setup as a retrospective study. Second, to challenge the test towards the hypothesized effect on fluoroscopy time reduction using laser guidance we selected only the easiest freehand guided biopsies based on target size and procedure time. The consequential dissimilarity in procedures likely affected the relative effect on fluoroscopy and procedure times reported in this study. To overcome these limitations, a large prospective study is required in the future.

Compared to the freehand technique, the use of laser guidance lengthened the procedure time by 6 minutes. This difference is probably caused partly by the extra time required for setting up the laser system, and partly by the selected freehand group since this group was selected not only on lesion size >20mm but also on the shortest procedure times.

CONCLUSION

In conclusion, this study indicates that adding laser guidance to cone-beam CT-guided biopsies provides visual feedback that significantly reduces fluoroscopy time, and consequently assists in reducing radiation exposure to both patient and interventional staff. In daily clinical practice, the cost in terms of prolonged procedure times will probably be marginal.

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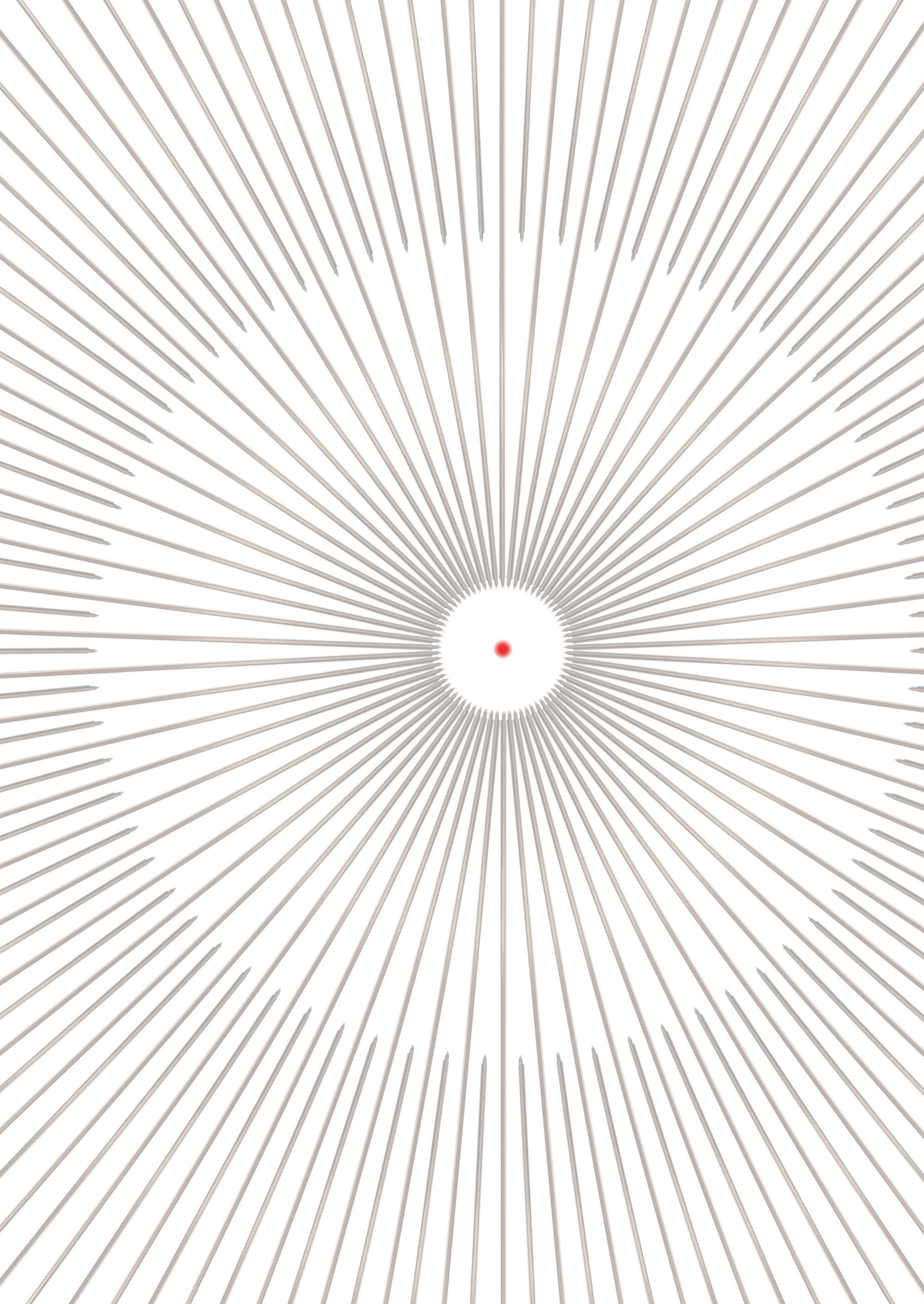

4

Laser guidance in CBCT-guided RF ablations of osteoid osteoma

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ABSTRACT

Purpose

To assess whether laser guidance can reduce fluoroscopy and procedure time of cone-beam computed tomography (CT)-guided radiofrequency (RF) ablations of osteoid osteoma compared to freehand cone-beam CT guidance.

Material and Methods

32 RF ablations were retrospectively analyzed, 17 laser-guided and 15 procedures using the freehand technique. Subgroup selection of 18 ablations in the hip-pelvic region with a similar degree of difficulty was used for a direct comparison. Data are presented as median (ranges).

Results

Comparison of all 32 ablations resulted in fluoroscopy times of 365 seconds (193-878 s) for freehand and 186 seconds (75-587 s) for laser-guided procedures ($P = 0.004$). Corresponding procedure times were 56 minutes (35-97 min) and 52 minutes (30-85 min) ($P = 0.355$). The subgroup showed comparable target sizes, needle path lengths and number of scans between groups. Fluoroscopy times were lower for laser-guided procedures: 215 seconds (75-413 s), compared to 384 seconds (193-878 s) for freehand ($P = 0.012$). Procedure times were comparable between groups; 51 minutes (30-72 min) for laser guidance and 58 minutes (35-79 min) for freehand ($P = 0.172$).

Conclusion

Adding laser guidance to cone-beam CT-guided osteoid osteoma RF ablations significantly reduced fluoroscopy time without increasing procedure time.

INTRODUCTION

Osteoid osteoma is a benign bone tumor that typically occurs in the extremities of children and young adults (1). The tumor presents with intense pain, which has been reported to be a result of the nidus (2), associated hyperostosis (3), or the neural elements in the reactive fibrous tissue (4). Excision or destruction of the nidus has been proven to be curative (5, 6). Traditionally treatment involved open excision of the osteoid osteoma, however this has been replaced by minimal invasive methods of nidus destructions to shorten hospital stay and recovery time (7). Various minimal invasive techniques have been described, such as percutaneous core drilling, percutaneous radiofrequency (RF) ablation and laser photocoagulation (5, 6, 8). The difficulty in these treatments is visualizing and targeting the small nidus (usually smaller than 15 mm diameter). Guidance techniques are therefore essential during these minimal invasive treatments. The use of cone-beam computed tomography (cone-beam CT) guidance for positioning RF needles in the nidus of the osteoid osteoma has been described previously (9). Advantages of cone-beam CT guidance compared to conventional CT guidance are improved patient access (10) and higher accuracy in double oblique needle placements irrespective of the angle of the needle path planning and the level of user experience (11).

Cone-beam CT guidance uses fluoroscopy imaging superimposed on the cone-beam CT scan with needle path planning to visualize the actual needle position (12). Two C-arm geometry positions are used to guide the needle with fluoroscopy to the nidus, namely the entry point view and the progress view (10). The entry point view is used to find the skin entry point and to position the needle in the planned angle. The space between the patient and the detector of the C-arm, however, is limited and makes it challenging to drill a hole through the bone to the nidus along the planned path. The progress view, perpendicular to the entry point view, visualizes the needle progression from skin entry point to the target in relation to the planned path. To guide the drill in a controlled fashion, it is necessary to switch multiple times between entry point and progress views. This method will most likely increase the required fluoroscopy time together with the radiation exposure to the operator. A possible solution could be the use of a laser guidance device. The laser guidance system visualizes the planned needle angulation and skin entry point. Combined with the depth information provided by the C-arm in progress view, all information for accurate drill progression is provided simultaneously.

The current retrospective study was performed to assess whether laser guidance in cone-beam CT-guided RF ablation of osteoid osteomas can reduce the required fluoroscopy compared to cone-beam CT-guided procedures using the freehand technique. We further assessed whether laser guidance can aid in optimizing these procedures in terms of procedure time.

MATERIALS AND METHODS

Radiofrequency ablation

All RF ablations were performed using cone-beam CT guidance (Allura Xper FD20; Philips Healthcare, Best, The Netherlands) in the interventional suite. Patient preparation included general anesthesia, grounding pads placement, and sterile covering. Each procedure started with acquiring a cone-beam CT scan with the location of the osteoid osteoma centered in the image field as much as possible.

In the reconstructed 3D volume, the nidus was identified and a safe straight needle path was planned from skin entry point towards the nidus. The navigation software (XperGuide, Philips Healthcare, Best, The Netherlands) projected this planned needle path on the fluoroscopy images during the procedure to provide real-time feedback on needle position and progression in relation to the planned path and target point.

The entry point view, in which skin entry point and target were superimposed, was used to locate the skin entry point and place the drill (OnControl Bone Lesion Biopsy System, Teleflex Medical, Morrisville, USA) in the angulation of the planned path (13). Rotating the C-arm to progress view, perpendicular to the needle path, allowed visualization of the drill-tip in relation to the nidus.

During drill progression, subsequent low dose- and collimated- cone-beam CT scans were acquired to confirm that the drill followed the planned needle path or to determine deviations from the path. These scans were acquired when desired by the performing interventional radiologist. In case of deviations caused by the amount of force put on the drill, the path of the drill was adjusted in a newly acquired cone-beam CT scan. Figure 4.1 shows examples of image guidance and cone-beam CT imaging.

After reaching the nidus, the drill was replaced by the RF electrode (StarBurst SDE 17 gauge, AngioDynamics, Latham, USA). To ensure that the tip was placed in the nidus, a final cone-beam CT scan was acquired. The electrode tip temperature was increased to 85°C and maintained for 4 minutes, ablating a sphere with <2 cm radius. After the ablation, the electrode was retrieved and the procedure ended.

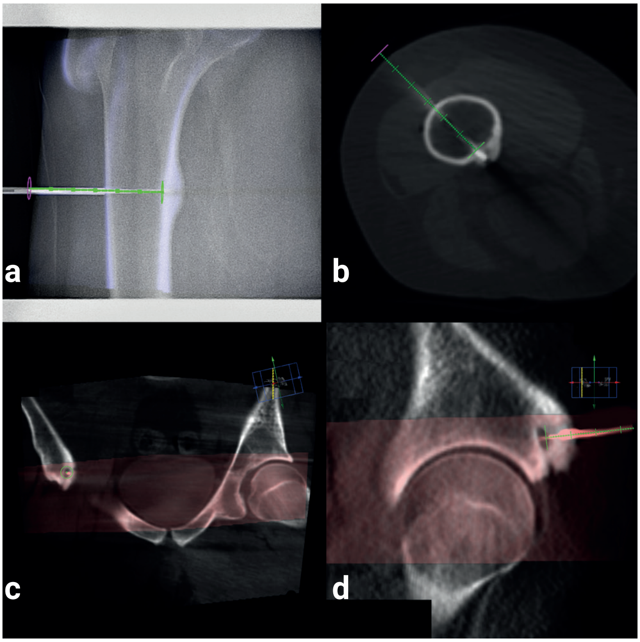


Figure 4.1: *Cone-beam CT images of 2 patients with osteoid osteoma.* ***a*** *shows the overlay during fluoroscopy guidance in the progress view.* ***b*** *shows a cone-beam CT-scan of the same patient, with the RF electrode along the planned needle path (green). In* ***c*** *and* ***d*** *the cone-beam CT-scan is fused with a previous CT-scan, the CT-scan is visualized in grey and the cone-beam CT-scan in red. In* ***c*** *the entry point view is visualized and* ***d*** *shows the progress view.*

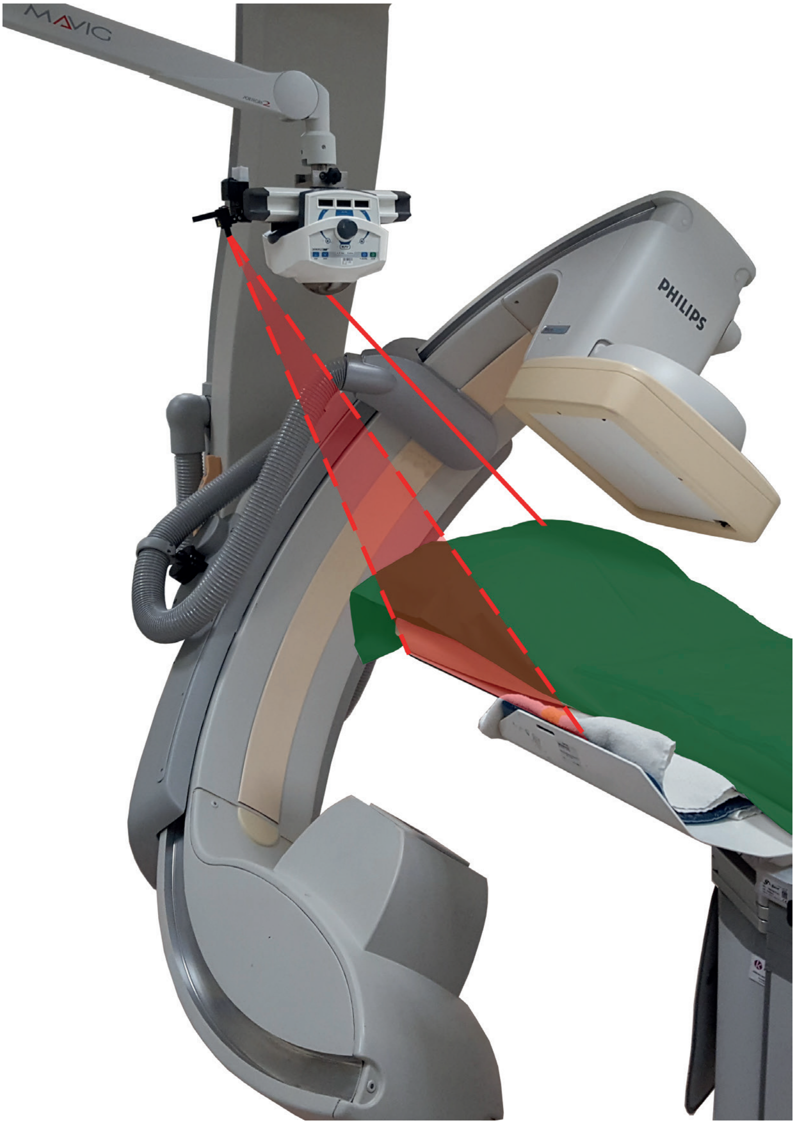


Figure 4.2: *Schematic presentation of the laser guidance setup. The guiding laser from SimpliCT is aimed along a planned needle path (straight line), while the plane laser (dashed lines) is aligned to the operating table. The C-arm is positioned in progress view.*

Laser guidance

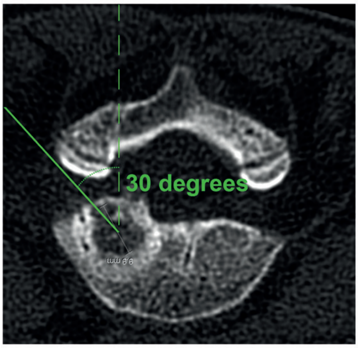
In procedures with laser guidance, placement and progression of the drill was assisted by a ceiling-mounted laser guidance unit (SimpliCT, Neorad AS, Oslo, Norway) acting as a laser pointing device.

First, the skin entry point was located using fluoroscopy and marked with a marker. The C-arm was then positioned in the progress view and the angles (in transversal plane and sagittal plane) of the needle path planning were fed into the laser unit. Hereafter the pointing laser could be positioned on top of the marked skin entry point, while the plane laser was aligned with the operating table (Figure 4.2). Using the laser pointer, the drill was placed in the angulation of the planned path. Throughout the drilling, the laser was used to keep the drill at the correct angulation, while fluoroscopy was used to check the depth of the drill. Cone-beam CT scans were acquired to confirm correct drill progression. The procedure including all laser guidance steps are visualized in Figure 4.3.

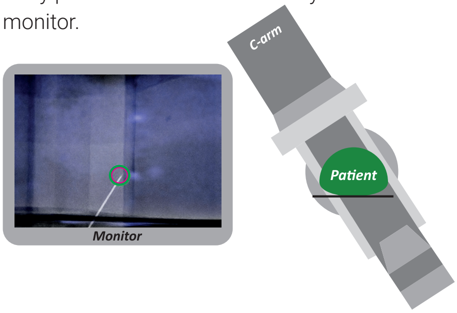
Protocol

This retrospective single center study was exempted from approval by the institutional review board. The laser guidance device is commercially available and is a routinely used aid during our institution's clinical interventional CT procedures. Only when tumor location or patient positioning did not allow the use of laser guidance, then only cone-beam CT guidance was used to position the drill on the target. The procedures were performed by 3 experienced interventional radiologists, all with 5 years or more experience in RF ablation for osteoid osteoma. Patients were included consecutively. Between June 2010 and January 2014, percutaneous RF ablation was performed in 32 patients with osteoid osteoma. In 17 cases laser guidance was used as additional guidance tool in needle placement. In the other 15 cases no additional needle guidance was used besides the cone-beam CT guidance. Henceforth the latter is referred to as freehand technique or freehand needle placement. Patient characteristics of both groups are provided in Table 4.1. This shows a large variety of locations for the osteoid osteoma. To accurately measure performance differences between both groups, a subgroup analysis was performed for 18 RF ablations with a similar degree of difficulty in the hip-pelvic region.

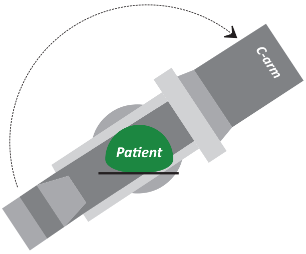
Step 1
Plan a needle path
In this example a needle path of 20 degrees



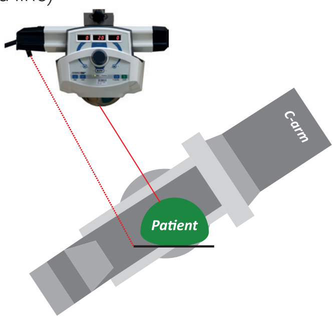
Step 2
Find and mark the entry point using fluoroscopy
- Place the C-arm in the entry point view
- Use needle and fluoroscopy to find the skin entry point visualized as a bulls-eye on the monitor.



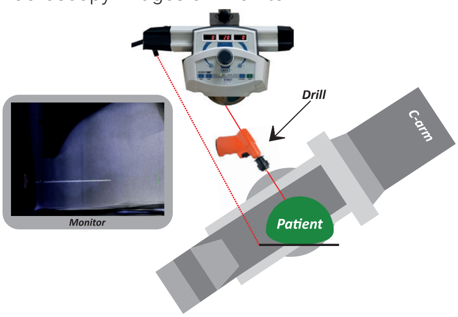
Step 3
Rotate C-arm in progress view



Step 4
Put angle of planned needle path in laser unit. Position laser-unit such that the guiding laser aims at the skin entry point (straight line) and the plane laser is in alignment with the operating table (dashed line)



Step 5
Progress drill while keeping end of drill in laserbeam until target is reached according to fluoroscopy images on monitor



Step 6
After the confirmation of the drill reaching the nidus using a CBCT scan , the drill was replaced by the RF electrode

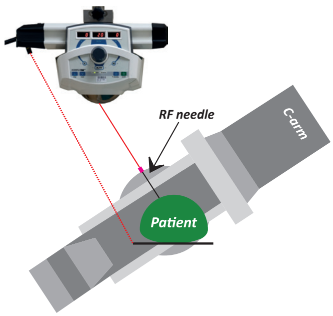


Figure 4.3: *A detailed visualization of the steps for laser guidance during cone-beam CT-guided RF ablation of osteoid osteoma.*

	Laser guidance	Freehand guidance
Number (male/female)	17 (14/3)	15 (10/5)
Age, median (range)	14 (4-34)	27 (9-55)
Location osteoid osteoma:		
• Hip-pelvic region	10	8
• Tibia/Fibula	4	2
• Humerus	2	2
• Tarsus	1	1
• Ulna	0	1
• Cervical vertebra	0	1

Table 4.1: *Characteristics of osteoid osteoma patients*

4

Parameters and analysis

Data of all parameters were retrospectively collected. Parameters provided by the imaging system were fluoroscopy time (in seconds), the number of acquired cone-beam CT scans and the dose-area-product (DAP) of fluoroscopy and cone-beam CT scans (Gy•cm²). The procedure time (in minutes) of the RF ablation was recorded, starting at the first cone-beam CT-scan and including laser setup time, and was stopped after the RF ablation was finished. Patient preparation and inducing anesthesia were not included. Technical success was defined as the RF-needle tip positioned directly in the nidus and along the planned needle path. Length and height of all patients were converted into body-mass-index (BMI) data.

Statistical analyses were performed with IBM SPSS Statistics (v22.0; IBM Corporation, Armonk, USA). Differences between the two groups were analyzed using the Mann-Whitney U-test. Two-sided *P*-values < 0.05 were considered statistically significant. Data are presented as medians with corresponding ranges.

RESULTS

Technical success was achieved in 100% of the RF ablations. For the total group of 32 RF ablations, adding laser guidance to the procedure resulted in a significant reduction of fluoroscopy time (*P* = 0.004). Fluoroscopy times were 186 seconds (75-587 s) vs. 365 seconds (193-878 s) for the laser procedures and the freehand procedures, respectively, indicating a reduction of 49% for laser-guided procedures (Figure 4.4). Procedure times were not significantly different between the two groups, with 52 minutes (30-85 min) in the laser guidance group and 56 minutes (35-97 min) in the freehand group (*P* = 0.355).

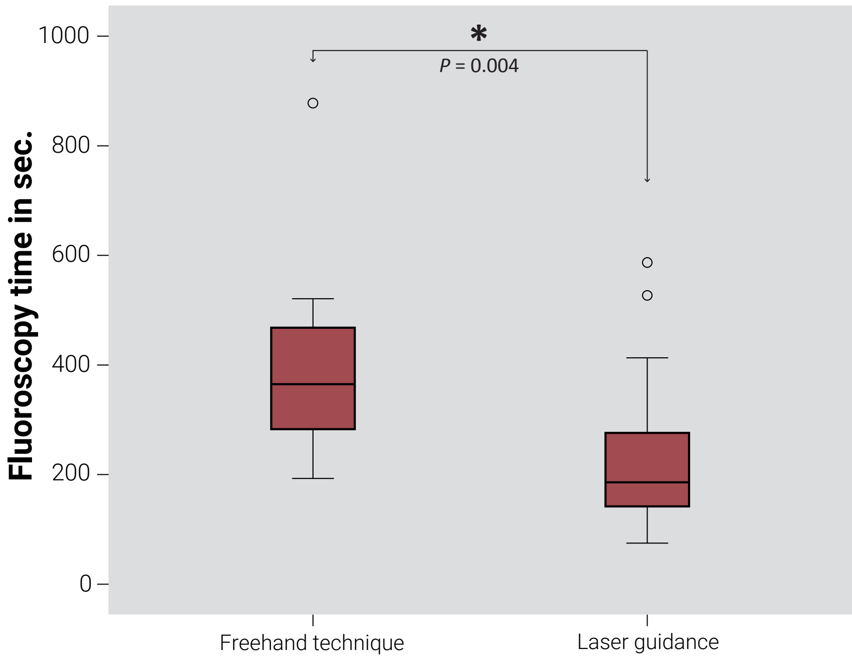


Figure 4.4: *Box plot representing the fluoroscopy times in seconds required to guide the needle onto the target per guidance technique, with a significant reduction using laser guidance (P = 0.004).*

The characteristics of the subgroup of 18 osteoid osteoma RF ablations in the hip-pelvic region are presented in Table 4.2. For both the laser guidance group and the freehand-guided group we found similar target sizes (*P* = 0.965) and lengths of needle paths (*P* = 0.372). Comparing fluoroscopy times, laser guidance significantly reduced the number of fluoroscopy seconds (*P* = 0.012). A median of 215 seconds (75-413 s) was necessary to guide the drill, compared to 384 seconds (193-878 s) for the freehand group. For both the number of cone-beam CT scans and procedure time no statistically significant differences were found. The median number of cone-beam CT scans for the laser guidance group was 4 (2-7) compared to 5 (3-7) for the freehand group. When laser guidance was used, the median procedure time was slightly lower with 51 minutes (30-72 min), while the median procedure time for the freehand group was 58 minutes (35-79 min).

	Laser guidance	Freehand	*P*-value
Osteoid osteoma locations	Femur: n = 9 Pelvic bone: n = 1	Femur: n = 5 Pelvic bone: n = 3	
Age (yr)	11 (4-34)	26 (16-54)	$P = 0.011$
Diameter of irradiated anatomy (cm)	19.4 (16.2-28.3)	27.5 (12.4-31.9)	$P = 0.052$
Target size (mm)	8 (6-10)	7.5 (6-10)	$P = 0.965$
Length needle trajectory (mm)	54 (36-80)	65 (31-113)	$P = 0.372$
Fluoroscopy time (s)	215 (75-413)	384 (193-878)	$P = 0.012$
Percentage collimated fluoroscopy	44 (12-65)	38 (0-74)	$P = 0.657$
No. of scans	4 (2-7)	5 (3-7)	$P = 0.308$
Procedure time (min)	51 (30-72)	58 (35-79)	$P = 0.172$

Table 4.2: *Characteristics of RF ablation of osteoid osteoma in hip-pelvic region*

For the freehand positioned RF needles in the hip-pelvic region, the median fluoroscopy DAP value was 41.9 Gy•cm² (3.8-68.5). With a median of 2.8 Gy•cm² (1.6-27.1), fluoroscopy DAP for laser-guided RF ablations was significantly lower ($P = 0.003$). The cone-beam CT DAP for the laser group was 9.3 Gy•cm² (1.7-77.2) versus 35.5 Gy•cm² (3.7-91.2) for the freehand group ($P = 0.068$). The large differences in DAP compared to the differences in fluoroscopy time and number of cone-beam CT scans is partly caused by the trend visible in the diameter size of the irradiated anatomy of the cone-beam CT scan ($P = 0.052$). The trend of smaller patients for the laser group is caused by the statistically significant difference in age between the groups ($P = 0.011$), a median age of 11 years (4-34) compared to 26 years (16-54) for the freehand technique group. The difference in age is reflected in the BMI, for the laser group the median BMI is 18 kg/m² (14-24) while the fluoroscopy group has a median BMI of 25 kg/m² (18-30) ($P = 0.006$).

DISCUSSION

The most essential finding of this study is that adding laser guidance to cone-beam CT-guided RF ablation of osteoid osteoma significantly reduces fluoroscopy time, without extending the procedure time.

Fluoroscopy has been reported to be 35-45% of the total effective patient dose in cone-beam CT-guided needle interventions (14, 15). Reducing fluoroscopy time by employing laser guidance can serve to reduce the radiation exposure to the patient. Laser guidance was previously reported in cone-beam CT-guided needle interventions in a laboratory setting using a phantom (16). The results of the laboratory study showed a similar percentage of reduction in fluoroscopy time as the RF ablation in this clinical study. Here, the fluoroscopy time reduction itself is attributable to the visualization of the planned drill trajectory, leading to more efficient positioning of the drill, a reduced number of corrective manipulations of the drill, and less switching between entry point view and progress view as reflected by the significantly reduced time to guide the drill.

Overall, the number of necessary cone-beam CT scans to complete the RF ablation procedures was higher compared to previously published cone-beam CT-guided needle intervention studies that used 2 to 3 cone-beam CT scans (14, 17, 18). This difference could be explained by the difference in types of intervention. The referenced studies present data on biopsies in soft tissues, whereas the presented RF ablations comprise needle placements in bones. Due to the greater force required to drill through bone, extremities move or rotate and total patient position can shift. In these latter cases the needle path planning based on the cone-beam CT no longer matches with the new situation and a new cone-beam CT is needed to adjust the planning. Patient fixation by a vacuum mattress could possibly reduce this effect.

Adding laser guidance to the procedure did not prolong total procedure time. Even though laser preparation and correct positioning takes several minutes, this is compensated for by the time saved during the remainder of the procedure. Several other factors that could have influenced the procedure time can be identified, such as the ease of drilling towards the nidus, the number of cone-beam CT scans acquired, how often the drill trajectory needs to be adjusted and the length of the drill trajectory. These factors are all likely to be reflected in the wide range in recorded procedure times (30-79 min).

There are some limitations to the presented study. The retrospective nature of the study in combination with the relatively low number of 18 RF procedures available for subgroup analysis made it difficult to use the data for dose comparisons. To be able to show an effect on fluoroscopy DAP, a larger prospective study is required. For our single expert center the number of patients which could be included is limited, as shown by the current study which spanned a period of 3 years, therefore a multicenter prospective study is recommended. Even though fluoroscopy time is a direct measure for the number of needle manipulations and required time to position the needle tip in the target, fluoroscopy DAP also reflects differences related to collimation, choice of protocol and size of irradiated volume. Therefore, the observed difference in DAP between groups could not be considered a direct effect of laser guidance. We did try to correct each DAP outcome for the differences in diameter size of irradiated anatomy, collimation per protocol used, number of frames per fluoroscopy second, type of protocol to prove the effect of laser guidance in DAP. However too many unknown variables have an effect on the outcome. We do know that the reduction in fluoroscopy times was a direct result of the use of laser guidance and reflected a relevant reduction in radiation exposure, irrespective of patient sizes or imaging protocols.

CONCLUSION

Adding laser guidance to cone-beam CT-guided osteoid osteoma RF ablation for drill alignment with the planned needle path, significantly reduced fluoroscopy time up to 50%, without increasing procedure time.

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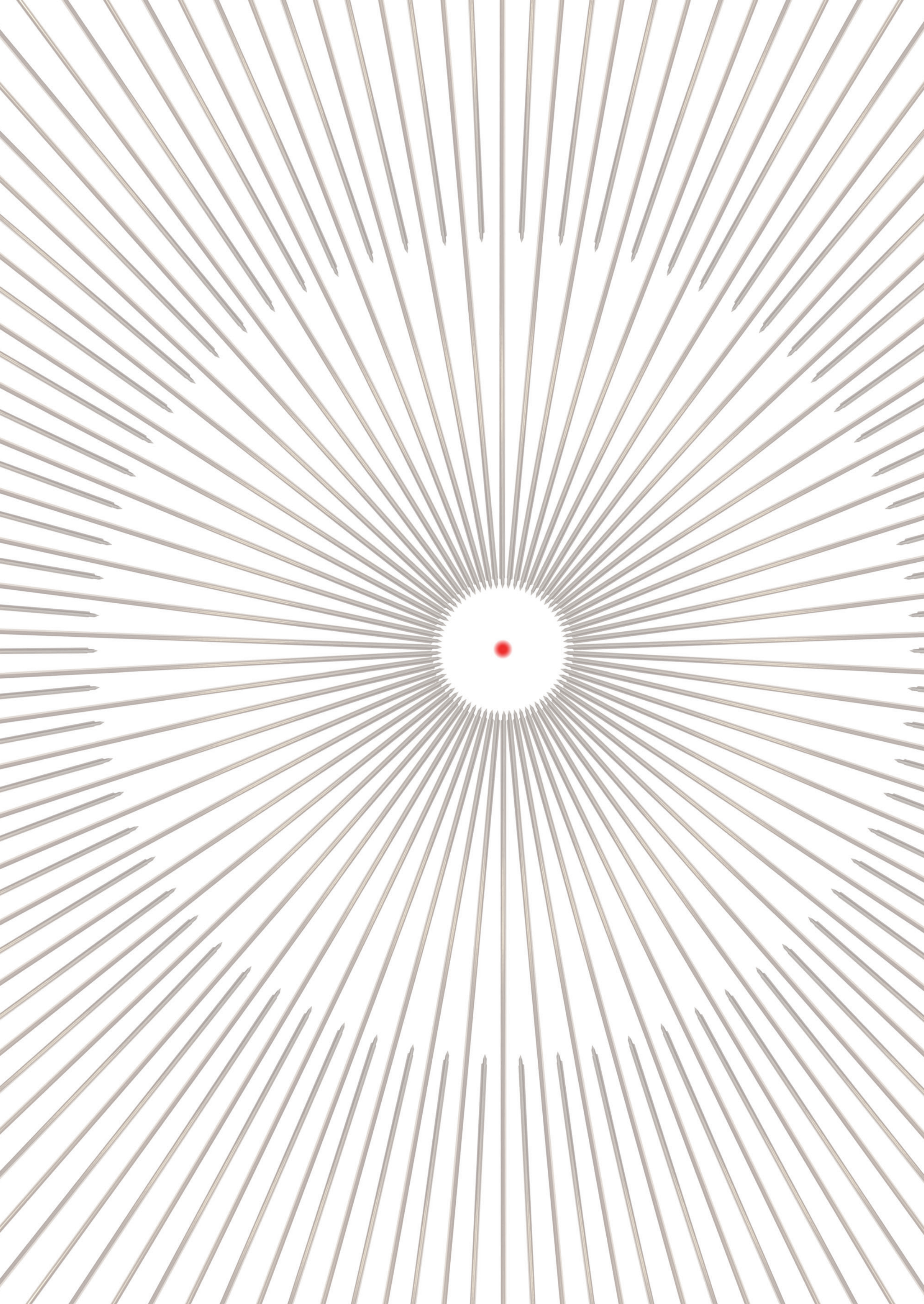

5

CT-guided puncture training using a phantom model: freehand vs. laser guidance

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Kroes MW, Hoogendoorn SP, de Lange F, Hoogeveen YL, Schultze Kool LJ
Laser guidance reduces the number of control scans in all phases of the learning curve in computed tomography-guided needle punctures: a phantom study

ABSTRACT

Purpose

To assess whether using laser guidance can shorten the training and learning curve of radiology-residents in CT-guided needle punctures.

Materials and methods

Fourteen trainees were divided into two groups to perform needle punctures using either laser guidance or freehand technique in a paraffin-gel phantom. Training was in four sessions at one week intervals. Each session entailed performing three simple and three difficult punctures. Each trainee participated in three sessions using either laser guidance or freehand technique. For the fourth session the trainees switched technique to measure the effect of training. For each puncture, needle placement time, number of control scans and accuracy were obtained.

Results

For both techniques the learning curve showed a reduction in needle placement time across the three consecutive sessions: 36% for simple and 42% for difficult punctures for the freehand group; 43% and 51%, respectively, for the laser group. In the third session, the laser group required fewer scans for needle positioning than the freehand group: one versus three scans, respectively ($P < 0.001$). Puncture accuracy did not differ between groups ($P = 0.64$). For the fourth technique-switching session, the only difference in comparison to the third session was needle placement time for difficult punctures using the freehand technique; time increased by 1.50 s/cm during the fourth session ($P = 0.043$).

Conclusion

The learning curve using either laser- or freehand technique is equal in terms of accuracy and time. Importantly, using laser guidance a significantly lower number of control scans was required, which signifies less radiation exposure to a patient.

INTRODUCTION

Computed tomography (CT) guided percutaneous needle intervention is a common procedure in the specialty of radiology (1-4). Training in radiology predominantly uses the traditional master-apprentice model in which skills are acquired through supervised direct patient contact (5). This also applies to CT-guided needle interventions. Training by means of the traditional model is time-consuming (6), especially for inexperienced trainees, but necessary to be able to learn the core skillset for this procedure. As well as the need for more efficiency and productivity, increasing radiation risk awareness reduces the training opportunities for the trainees (7). Inexperience may have implications for patient safety, complication rates, procedure times, number of necessary needle passes and radiation dose to both staff and patient (8).

The core technique of CT-guided needle interventions is the placement of a needle according to a needle path planning, thus the translation from the planning on CT-scans in two dimensions to the placement in a three dimensional environment. Several studies have shown that this step can be practiced in simulation-based training, resulting in a statistically significant improvement in procedural and technical skills (9, 10).

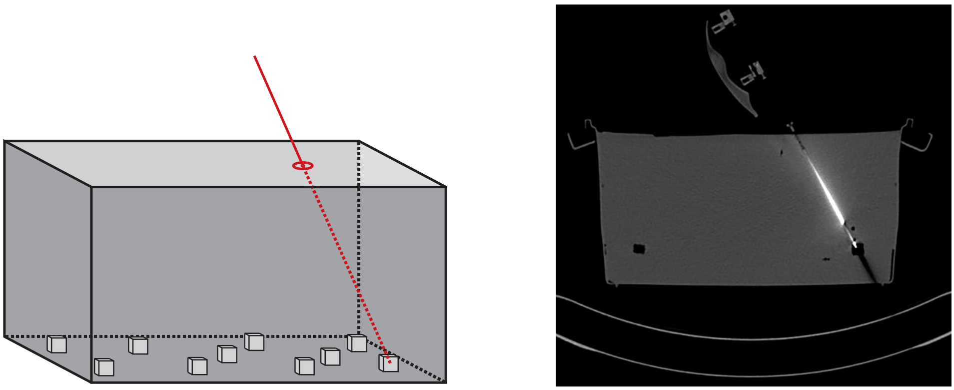
Besides simulation-based training, vendors develop new navigational devices to assist the operator and to simplify the CT-guided percutaneous needle interventions. At our institution a laser guidance system is installed in the CT-suite. Compared to the freehand technique, laser guidance systems have proven to increase accuracy on the initial needle placement (11), reduce radiation exposure and improve the workflow (12), while the handling- and set-up times are only marginally longer (13).

The objective of this study is to assess whether laser guidance has a similar effect on simulation-based training. The learning-curve of procedures with laser-guidance were compared with conventional freehand guided procedures as performed by trainees without CT-intervention experience. The learning curve parameters used were needle placement time, accuracy of needle placement and number of control CT-scans.

MATERIALS AND METHODS

Laser guidance system

The laser guidance system added to the CT-guided needle interventions in this study is SimpliCT (SimpliCT, NeoRad AS, Norway). This guidance system for percutaneous needle interventions acts as a laser pointing device to visualize a planned needle path for the operator to a maximum angulation of 45 degrees in both the axial and sagittal plane. The system is ceiling mounted using a Portegra2 arm (Mavig GmbH; Munich; Germany), making it possible to position the laser unit on both sides of the CT-table. A plane laser is used to align the laser to the coordinate system of the CT-scanner (Siemens Somatom Sensation 64; Siemens Healthcare GmbH; Erlangen; Germany).



a b

Figure 5.1: *(**a**) Schematic presentation of the in-house made phantom with ten 1 cm³ targets. (**b**) CT slice of the used phantom with a needle inside one of the ten targets.*

Phantom

Needle interventions were performed on an in-house made phantom consisting of a plastic container with dimensions of 26x15x13cm filled with clear candle gel (Paraffin gel, Creartec GmbH; Lindenberg im Allgäu; Germany). Ten targets consisting of radiolucent poly-urethane foam with size 1x1x1cm were embedded in the candle gel at a depth ranging from 8 to 10cm (Figure 5.1). The phantom was tested by one of our institute's experienced interventional radiologists who concluded that the puncture in the candle gel phantom was comparable to a basic soft tissue puncture. For each session the phantom was covered with a clean sheet of non-transparent paper so as to be able to mark a skin entry point according to the needle path planning and to conceal the target positions in the clear candle gel. Following each weekly session, the phantom was heated to melt the needle tracts formed in the candle gel. All needle interventions were performed using an 18-Gauge needle (Vigeo, S. Biagio, Italy).

Subjects and protocol

Based on sample size calculations using data from in-house procedures in which we found a 25% reduction in procedure time when laser guidance was added to CT-guided biopsies, a total number of seven trainees were required for each group. Fourteen radiology-trainees without experience in CT-guided interventions were randomly divided into two groups; one group using laser guidance, the laser group, and one group using the freehand technique, the freehand group. Group characteristics are given in Table 5.1.

	Freehand group	Laser group	P-value
Age (yr) (mean ± SD)	28.1 ± 1.9	29.0 ± 2.4	*P* = 0.48
Months of radiological experience	5.6 ± 7.0	1.9 ±2.0	*P* = 0.20
Gender (male/female)	5/2	5/2	*P* = 1.00

Table 5.1: *Group characteristics*

Each trainee was allotted four puncture sessions; each session was separated by one week and each session consisted of six punctures. The first three punctures were defined as simple punctures, with a needle path only angled in the transversal plane. The last three punctures were defined as difficult punctures, angulated in at least the sagittal plane and sometimes in combination with angulations in the transverse plane (Table 5.2). Trainees were instructed to position the needle-tip inside the target, as central as possible.

For each group of trainees, the first three sessions were dedicated to the initially randomly allotted guidance technique, i.e. either freehand or laser guidance. For the fourth session the groups switched guidance technique.

	Session 1	Session 2	Session 3	Session 4
Puncture 1	0/0	15/0	5/0	0/0
Puncture 2	20/0	25/0	30/0	20/0
Puncture 3	30/0	35/0	40/0	30/0
Puncture 4	0/10	5/15	10/5	0/10
Puncture 5	10/10	15/15	20/10	10/10
Puncture 6	20/20	25/25	30/20	20/20

Table 5.2: *Angulations of needle punctures per session. Numbers indicate degree of angle in transversal plane/ degree of angle in sagittal plane.*

All trainees received illustrated instructions on how to perform a freehand- or laser-guided needle intervention one week prior to their first session. Just prior to the first session, each trainee followed the illustrated instructions again in the CT-room as a practical step-by-step plan. During the procedure, the trainees needed to follow the steps without a copy of the instructions and perform the needle interventions by themselves including the setup of the laser guidance system. One of the authors (MK or SH) was always present during the punctures to operate the CT-scanner, select the scanning protocols, plan the needle paths and visualize the progression of the needle in the control scans. The puncture protocols with the smallest slice thickness were used for the CT-scans (120kVp, 100mAs, 0.6 mm slice thickness). The puncture procedure was finished when the trainee was satisfied with the position of the needle after performing a final control scan.

Parameters

Needle placement time (in seconds) was recorded as the time between the topogram and the last acquired control-scan including setup time for the laser guidance system. The average needle placement time (in seconds) was calculated for each session per person, both for simple and difficult needle-passes. Each week the angles of the punctures were the same for each trainee. However, these repeated punctures were not performed on the same target every week. For this reason, while angulations of the needle path were the same, the punctures between trainees differed in needle path length. Needle path lengths varied between 5 – 29 mm and needle puncture times were therefore corrected for the length of the needle path by dividing the needle placement times by the respective needle path lengths. The accuracy of the needle placement was defined as the distance (in millimeters) between the needle-tip and the center of the target. Needle-tip to target center distances were obtained using the 3D Slicer open-source software platform (version 4.4) (14). The number of control scans necessary to position the needle inside the target was recorded for every puncture.

Statistical analysis

Statistical analysis was performed with SPSS v.22 (SPSS Inc., Chicago, IL). To analyze the learning curve and compare the changes in the needle placement time during the first three sessions, a linear mixed model analysis was performed. The data of the number of control scans were represented as medians with corresponding ranges and analyzed using the Mann–Whitney U test. For the accuracy results an independent-samples t-test was used and these results were expressed as means ± standard deviations. Differences were considered statistically significant for $P < 0.05$.

RESULTS

5

Needle placement time

Ten targets were positioned inside the phantom, all with a depth ranging from 8 to 10 cm. For both the puncture groups (simple and difficult) the needle placement time decreased across the three sessions (Figure 5.2). The freehand group reduced their needle positioning time for simple punctures with an average of 36% ± 17. The laser group showed a reduction of 43% ± 17 in needle placement time, which means a steeper reduction in time during the puncture sessions. The difficult punctures showed similar results. The average of the freehand group showed a reduction in placement time of 42% ± 17 after three sessions, for the laser group this reduction in time was 51% ± 17. Irrespective of the degree of difficulty of the punctures, we found no difference in the learning curves between groups ($P = 0.662$ for simple punctures and $P = 0.422$ for difficult punctures).

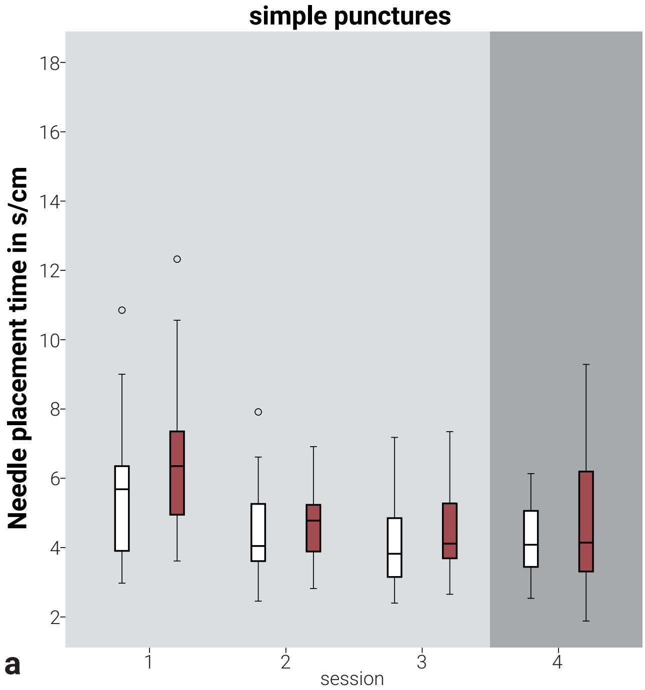
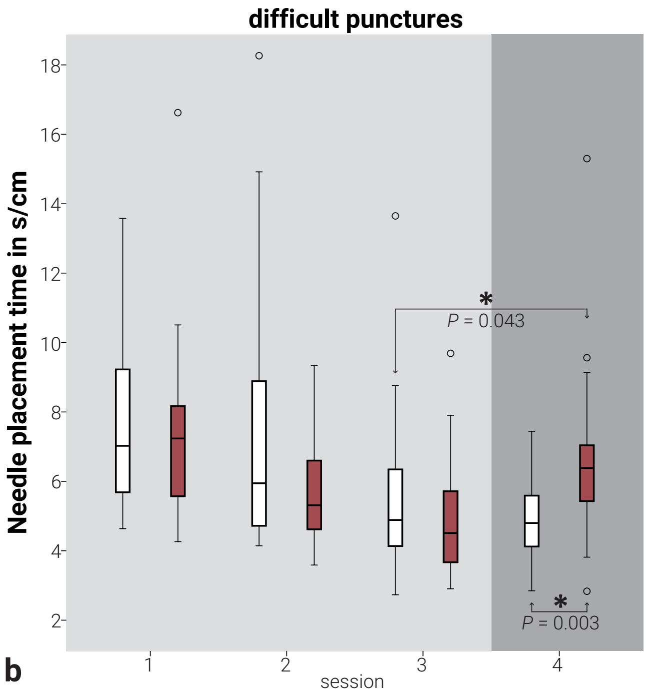


Figure 5.2: *Boxplot depicting the needle placement time in seconds per centimeter for each puncture session for the laser and freehand groups. Figures **a** and **b** give the outcomes for simple and difficult punctures, respectively. For session 4 the groups changed guiding techniques: the freehand group used laser guidance and the laser group used the freehand technique. No difference was found in the learning curves between groups;*



P = 0.662 for simple punctures and P = 0.422 for difficult punctures.In the fourth session the laser guided punctures, now performed by the freehand group, showed a shorter needle placement time (P = 0.003). The laser group, now employing the freehand technique, showed an increase in needle placement time compared to the results of the freehand group in their third session (P = 0.043).

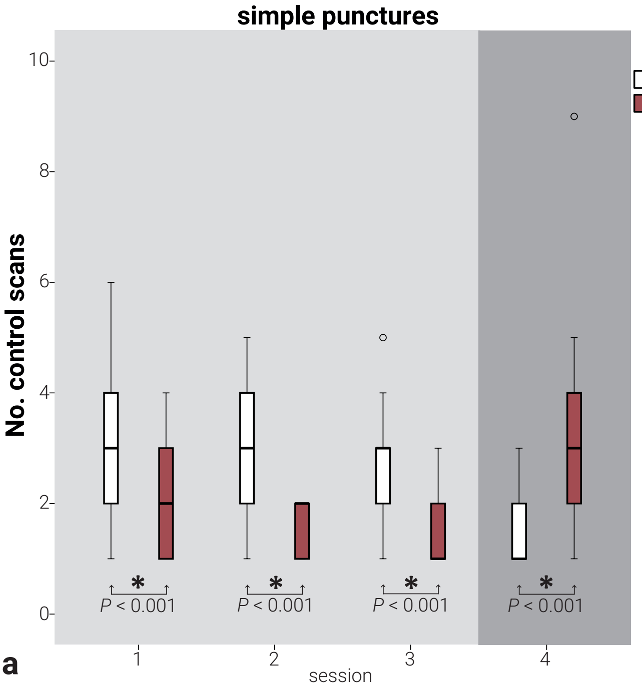
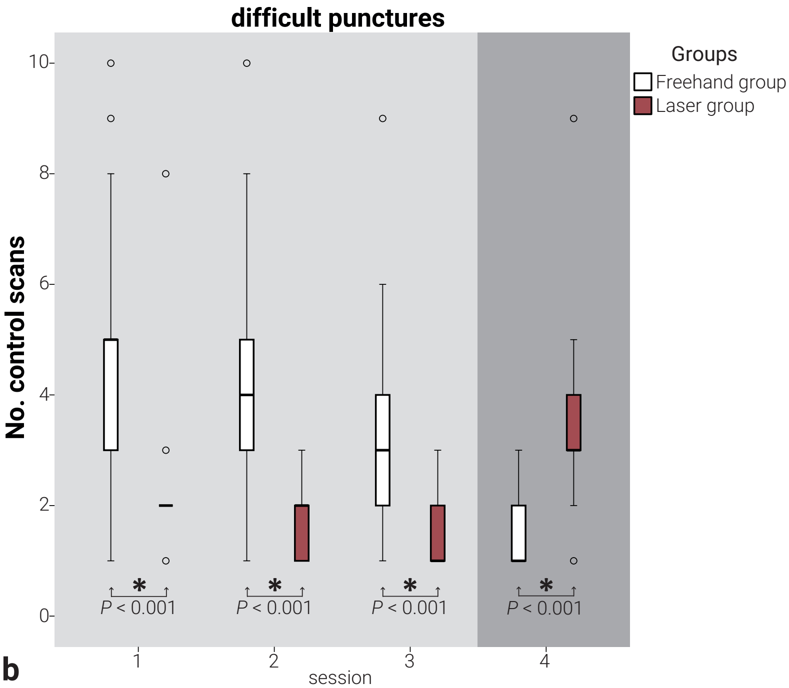


Figure 5.3: *Boxplot depicting the number of control scans for each puncture session. Figure **a** shows the number of control scans for the simple punctures and figure **b** for the difficult punctures. Asterisk represents a statistically significant difference between the freehand group and the laser group. For session 4 the groups changed guiding techniques, the freehand group used laser guidance and the laser group used the freehand technique.*



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Accuracy

The trainees were instructed to position the needle-tip as central as possible inside the target. For the freehand group no differences were found between sessions in needle-tip accuracy. For the laser group the learning curve showed an increase in accuracy from the first to the second session, with an average increase of 1.1 mm ($P = 0.001$). No difference in accuracy was found between the second and third sessions. For all sessions overall, the average distance for the needle tip to the absolute center of the target for the freehand group was 4.2 mm ± 1.4 compared to 3.7 mm ± 1.6 for the laser group ($P = 0.64$).

Control scans

Throughout the three sessions the number of control scans necessary to position the needle inside the target for both puncture difficulties was lower for the laser group in comparison to the freehand group ($P < 0.001$) (Figure 5.3). From the first to the third session, the laser group went from 2 control scans to only 1 control scan, irrespective of the puncture difficulty. The freehand group needed 3 control scans for simple punctures throughout the three sessions, while for difficult punctures the number of control scans was reduced from 5 scans for the first session to 3 scans in the third session.

Session 4

The trainees switched technique for the fourth session. The freehand group used laser guidance and the laser group used the freehand technique for the needle punctures.

For the simple punctures no differences in needle placement time were found between laser guidance and the freehand technique in this fourth session ($P = 0.343$) (Figure 5.2). For the more difficult punctures, laser guidance reduced the needle placement times in comparison to the freehand technique; median needle placement times were 4.80 s/cm (2.85 – 7.44) and 6.38 s/cm (2.83 – 15.30) for the laser guided and freehand techniques, respectively ($P = 0.003$). When the laser guided needle placement times in the fourth session were compared to those from the third session, no differences were found between simple ($P = 0.567$) and difficult punctures ($P = 0.501$). Comparing the freehand results between the third and fourth session, no differences were found for simple punctures ($P = 0.261$). However, comparing the more difficult freehand punctures, an increase in needle placement time of 1.50 s/cm was observed for the fourth session ($P = 0.043$).

In the fourth session, laser guidance significantly reduced the need for control scans for both types of puncture difficulty ($P < 0.001$) (Figure 5.3). Using laser guidance required only 1 control scan, irrespective of the degree of difficulty. By contrast, the freehand technique required 3 control scans for both angulated and double angulated punctures. Comparing the fourth to the third session, the total number of control scans was the same.

No difference was found between the two groups in needle tip distance to target ($P = 0.709$) in the fourth session, namely 3.8 mm ± 1.6 for the laser guidance technique and 3.7 mm ± 1.4 for the freehand technique. Compared to the third session, no differences were found for laser guidance ($P = 0.447$) and freehand technique ($P = 0.095$).

DISCUSSION

The objective of this study was to compare the learning curve of trainees in CT-guided punctures using either laser guidance or the freehand technique. These two CT-guided techniques follow a very similar learning curve for all but one of the measured parameters, namely the number of control scans. Employing laser guidance results in a significantly lower number of control scans compared to the freehand technique. Fewer control scans means fewer numbers of needle manipulations and less radiation exposure to a patient, two important aspects for CT-guided needle punctures.

The needle placement time decreased across the three sessions for both groups, indicating the effects of learning by means of repeated needle punctures. The slightly extended needle placement time using laser guidance is only minimal and after three puncture sessions similar to the freehand technique even though the trainees using laser guidance were also required to setup and position the laser system themselves.

Although this study was not aimed at evaluating the laser system used, it does give some indication on the ease of use of such a system for novices. Other navigational devices and tools like iSYS1 (iSYS Medizintechnik GmbH, Austria), CAS-ONE IR (CAScination AG, Switzerland) and Maxio (Perfint Healthcare, India) show an extension of several minutes for setting up and positioning the device for needle guidance alone (15-17). At the end of our puncture sessions, the needle placement time is between the 8 and 9 minutes per puncture, which is in line with other CT-guided punctures in phantom and animal models (12, 18, 19). It should be noted that the needle placement times discussed in this study are only an indication for the time needed in a clinical procedure to actually position the needle as part of the total procedure time, which comprises more aspects, such as patient preparation and treatment time.

In three sessions, the freehand group reduced the number of control scans to position the needle to 3 scans. The laser group reduced the number of control scans from 2 to 1 control scan in both angulated and double angulated procedures. When the laser group switched to the freehand technique, the number of control scans increased to the level of the freehand group in the third session. Vice versa, the freehand group when switched to laser guidance used a similar number of control scans to the third session of the laser group. This suggests that the use of laser guidance increases a trainee's confidence in their performance of needle positioning, resulting in a lower number of needle manipulations even when changing to a freehand technique. On the other hand, since the number of control scans for the freehand technique would not go below the 3 control scans, it appears that the training protocol itself had a limited effect on decreasing the total number of control scans. Therefore, to attain an as low as possible number of control scans, our study indicates that laser guidance should also be used beyond these training sessions, namely in clinical practice. This effect of laser guidance on reducing the numbers of control scans has been published previously (20).
In terms of accuracy, adding laser guidance to the needle puncture procedure did not show a difference compared to the freehand group, with both techniques in the range of 3 to 4 mm from the absolute centre of the target. This result is in line with other CT-guided punctures using puncture phantoms (17, 18).

There are some limitations to the presented simulation study. In this study no control group of experienced radiologists was available for a direct comparison to the expertise level of the trainees. However, previously published studies show comparable numbers of control scans to that found for the laser and freehand groups at the end of this study (21-23). Therefore, the level of experience gained by our trainees seems to have met the level of experienced radiologists. The results, however, were only acquired on a phantom. The fact that the phantom used in this study is a limited representation of a patient, without the possibility to simulate respiratory or target motion, a follow-up study on the performance of the trainees in the clinical setting is warranted.

In conclusion, the learning curve for performing punctures using either the laser- or freehand technique is almost equal in terms of accuracy and needle placement time. Importantly, using laser guidance a significantly lower number of control scans were required compared to the freehand technique, which signifies less radiation exposure to a patient. Simulation training using either one of these guidance techniques can be a useful tool to prepare the trainees for in-vivo CT-guided punctures.

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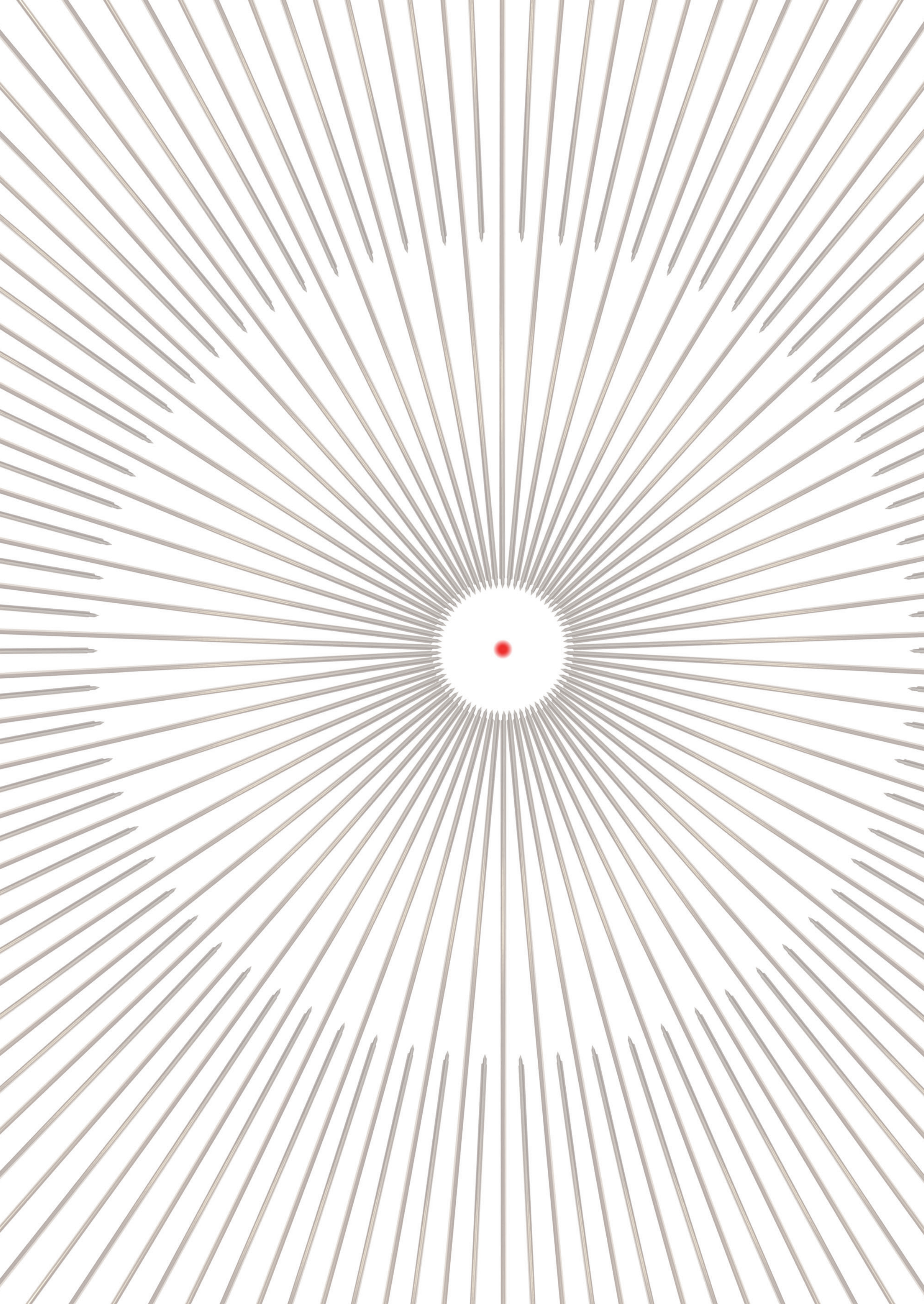

6

Catching breath: monitoring respiratory motion directly using ultrasound

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In preparation as

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Catching breath: monitoring respiratory motion directly using a novel ultrasound based monitor; a feasibility study

ABSTRACT

Purpose

A respiratory monitoring device was developed employing ultrasound to monitor respiratory motion directly and providing real-time readily interpretable feedback to the patient. Available monitors use indirect measures for respiratory motion, such as chest wall or abdominal deformation. The monitor could possibly assist image-guided punctures, minimizing image-registrations for PET-CT and assist patients in breathing cycles during radiotherapy. The purpose of this study was to assess the feasibility, accuracy and limitations of this technique.

Materials and methods

Respiratory motion was monitored in nine healthy volunteers. The monitor consists of four 3.5MHz ultrasound transducers each consisting of eight piezoelectric-elements, small enough to be fitted between ribs. The piezoelectric-elements functioned to monitor the pleural line. Signals were correlated to the diaphragm movement derived from M-mode recordings using a clinical ultrasound system. B-mode recordings from the clinical system were acquired for correlation analyses of the visceral pleura position, to measure the monitor accuracy. To define the limitations of the monitor, a BMI increase was simulated (16 mm thick polymer-flap between skin and transducer); and with the volunteer in prone position, the transducer was positioned on the volunteer's back.

Results

A strong correlation was found between the monitor signal and diaphragm movement as derived from ultrasound imaging (*Pearson* r = 0.91-0.99). The monitor showed a median accuracy of 2.8 mm (range 1.8-5.2 mm). Increasing the BMI by 5 kg/m^2 decreased the mean signal intensity by 17% (15.2 ± 1.4 vs. 17.8 ± 1.6; P = 0.002) but remained well distinguishable. Monitoring respiratory motion was possible with volunteers positioned both prone and supine (P = 0.719).

Conclusion

The proposed technique shows to be an accurate, non-invasive, real-time respiratory monitor. Future work will involve a feedback system design upgrade for an easier signal interpretation.

INTRODUCTION

Respiratory motion affects all tumour sites in the thorax, abdomen and pelvis (1, 2). For example, lung nodules can displace more than 20 mm during only one respiratory cycle of shallow breathing (3). Radiology (4), radiotherapy (5) and nuclear medicine (6) must cope with this motion to perform their therapy and diagnostics. Within the field of radiology for example, respiratory motion has a large effect on (cone-beam) CT-guided percutaneous needle interventions. In most cases breath-hold instruction techniques are applied for which accuracy of needle placement is often critically dependent on the skill of the radiologist and the patient's compliance. Furthermore, the diagnostic accuracy decreases with smaller lesions and longer needle paths (7).

Besides the typical instruction-based breath-hold techniques, a number of devices have been developed to assist the medical specialist by monitoring respiratory motion using either external or internal markers. The invasive character of the internal markers can only be justified for use in the field of radiotherapy. External markers use either the combination of infrared cameras with reflective markers positioned on the thorax of the patient to provide optical tracking (8) or pressure-sensitive belt systems that register chest or abdomen expansion during respiration (9). A limiting factor of external markers is that these provide indirect measures, and their ability to correlate respiratory motion to tumour motion is highly sensitive to their positioning on the patient (10). A previous study advocated the abdomen as the best location for external markers as the abdominal region provides the largest body expansion during normal breathing (11). In general, the challenge is to deal appropriately with the fact that patients change the type of breathing in uncomfortable settings, resulting in differences in intensity of signals measured by these external devices. The ability to monitor diaphragm motion directly and non-invasively is anticipated to significantly improve the precision of breathing motion control over these external marker techniques.

Ultrasound has proven to be fast, simple, accurate and reproducible in its ability to monitor diaphragm movement (12). Previous studies have shown the possibility to determine the diaphragmatic excursion, diaphragmatic contraction, inspiration time and duration of the breathing cycle (13, 14). Alternatively, the visceral pleura-lung border reflects a high percentage of the ultrasound beam back appearing as a bright echogenic line, the pleural line (15). This line can also be monitored to provide real-time and direct feedback of the breathing motion, moving forward and backward during the breathing cycle; an advantage being its superficial position. Downsides of using the current clinical ultrasound systems in breath-hold monitoring are that fixation of the transducer on the patient is cumbersome and that patients cannot easily interpret the acquired signals.

We present a newly developed breath-hold monitoring device employing ultrasound to monitor respiratory motion of the pleural line directly and providing real-time readily interpretable feedback to the patient. The purpose of this study was to assess the feasibility, accuracy and limitations of this technique.

MATERIALS AND METHODS

Subjects

Nine healthy volunteers, 1 female and 8 males, average age of 35 years (range 22-50), with an average BMI of 24 kg/m² (range 20-28) participated in the study (Table 6.1). Informed consent was obtained from all volunteers.

Volunteer	Age (yr)	Gender	Length (cm)	Weight (kg)	BMI (kg/m²)	Experiment nr.	Increase BMI by fat flap (kg/m²)
1	47	Male	174	85	28.1	1, 2	n.a.
2	27	Male	188	87	24.6	1, 2	n.a.
3	50	Female	180	80	24.7	1, 2	n.a.
4	46	Male	174	77	25.4	1, 2	n.a.
5	46	Male	176	68	22.0	2	n.a.
6	27	Male	170	58	20.1	2, 4	n.a.
7	22	Male	186	75	21.7	2, 3, 4	26.9
8	23	Male	170	65	22.5	2, 3, 4	28.1
9	23	Male	183	82	24.5	2, 3	30.1

Table 6.1: *Volunteer characteristics.*

The breath-hold monitor

Four small commercially available 3.5 MHz linear ultrasound transducers (Vermon, Tours, France) were mounted in a soft rubber housing (Fig. 6.1). The transducers were small enough to be fitted in between the ribs. Each linear array transducer, with a size of 28 mm by 5 mm, consisted of 8 piezoelectric elements with a fixed elevated focus of 35 mm. Ultrasound gel was applied between skin and transducer, while the rubber housing was taped to the volunteer. Inhouse software, based on LabView 2012 (National Instruments, Austin, USA), was used to readout the 32 elements in real-time and to visualize these signals on a monitor as a feedback system to the volunteer. With the transducer positioned on the volunteer in either intercostal space 7 or 8, the transition from thorax to abdomen was visualized. A strong signal, putatively of the pleural line moving along the transducer array led to a white horizontal bar on the monitor. To minimize the surrounding signals the gain of the real-time image was adjusted such that only the pleural line signals remained. The intensity of the monitor signal was obtained from the LabView data. The signals were in a 100 step greyscale, from white (0), the highest signal intensity, to black (99), the lowest signal intensity. Before commencing with the actual experiments, the volunteers were made familiar with this signal in a short training session in which they were asked to inhale and exhale three times while the signal increase and decrease on the feedback monitor was explained to them.

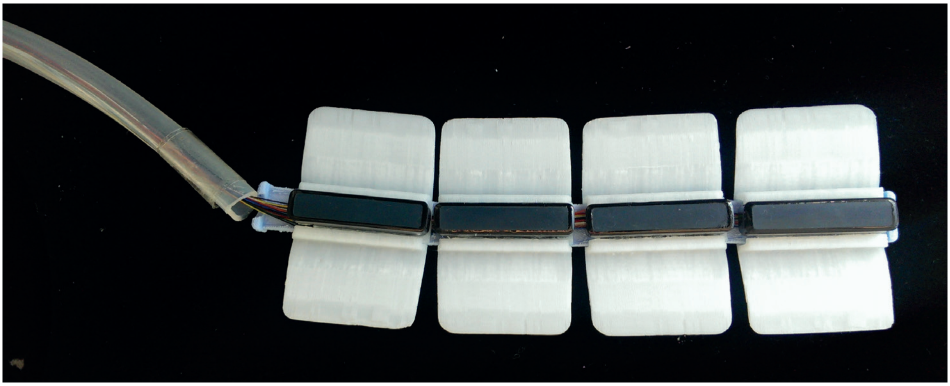

Figure 6.1: *Image of transducers (black) positioned in the housing (white).*

Breathing motion obtained by ultrasound

A commercial ultrasound system (Vingmed System 5, GE Healthcare, Aurora, USA) was used for M-mode sonography to record diaphragm motion and for B-mode recording of the pleural line. The analogue video transmission of the ultrasound system was subsequently digitized (video converter ConvertX PX-AV200U (Plextor, Freemont, USA); converter software

(Presto! Digital Converter 1.06, NewSoft Technology, Taipei, Taiwan)). M-mode sonography was performed by positioning of the transducer on the mid-clavicular line below the costal margin. For the B-mode recordings, a frame was used to position and hold the transducer fixed on the volunteer. In this set up the transducer was positioned on the intercostal space on the opposite side of the breath-hold transducer to monitor the transition from visceral pleura to abdomen.

Experiment 1: Correlation of the breath-hold monitor signal to breathing motion

The time-dependent signal of the monitor was correlated to the diaphragm motion recorded by M-mode ultrasonography. This experiment was performed on four volunteers. The timings of the diaphragmatic contractions were extracted from the M-mode data using video-editing software (Premiere pro CS4, Adobe, San Jose, USA). The sampling rate of the transducer array signal was 10 Hz compared to 25 frames per second of the M-mode recordings. The correlation between monitor and ultrasound data were determined by the Pearson's product-moment correlation coefficient. Statistical analysis was performed with SPSS v.22 (IBM, Armonk, USA).

Experiment 2: Accuracy of the breath-hold monitor

The volunteers were instructed to hold their breath while watching the feedback monitor and to remember the pleura-signal position located on the feedback monitor. After this first breath-hold, the volunteers were asked to continue breathing for 3 cycles and to subsequently hold their breath with the pleura-signal on the same position on the monitor as during the first breath-hold attempt. This protocol continued until the third breath-hold.

The feedback monitor recorded the pleural line movement on the right side of the volunteer and the ultrasound system on the left side. Figure 6.2 shows the setup of this experiment. All nine volunteers participated in this experiment.

The position of the pleural line recorded in B-mode were obtained using video-editing software (Premiere pro CS4, Adobe). The position was defined as the average position of the pleura during the period of the breath-hold. Accuracy was defined as the difference in (average) position of the pleural line in the B-mode recordings from the second and third breath-hold, relative to the position that was chosen during the first breath-hold. The resulting accuracy is presented in mm as median (range).

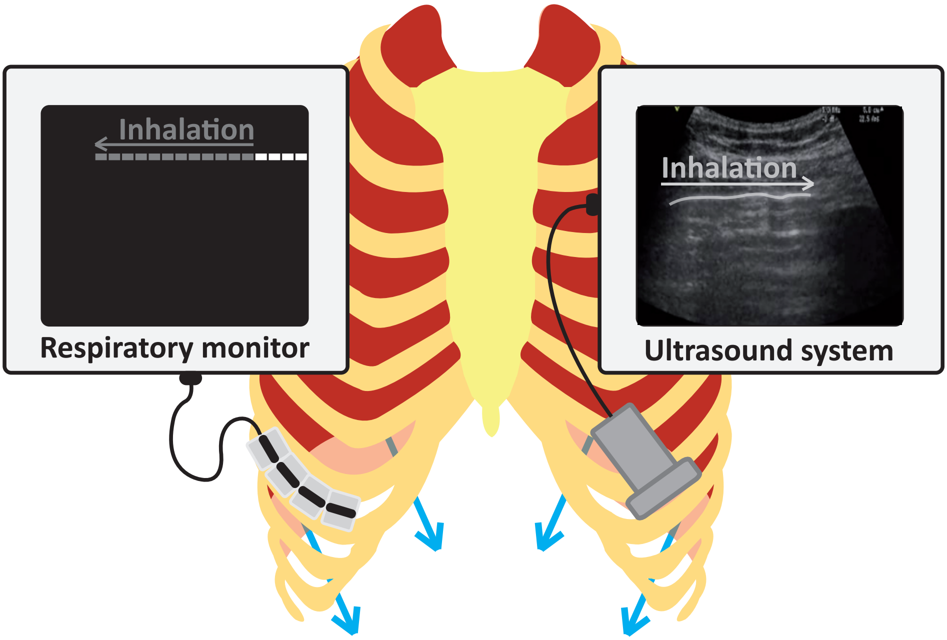

Figure 6.2: *Diagram of the experimental setup. During an inhalation the diaphragm contracts and moves downward expanding the lungs as visualized by the blue arrows. The expanding of the lungs is monitored by both the monitor and the ultrasound system. To measure the accuracy of the breath-hold monitor (second experiment), the breath-hold monitor was positioned on one side of the volunteer and the ultrasound system on the other.*

Experiment 3: Sensitivity of the breath-hold monitor signal to BMI

For three volunteers the BMI was artificially increased by using a 16 mm polymer flap (Eurosil 10 Orange; Schouten SynTec, Mijnsheerenland, the Netherlands), prepared in house and simulating extra fat tissue positioned between transducer and skin. This polymer flap has a slightly higher density (1.15 g/cm³) compared to human fat-tissue (0.91 g/cm³). The effect of this polymer flap on BMI of the volunteers was determined by using the body surface calculations by Mosteller (16). In obesity the increase in total body surface is mainly attributable to the surface increase in legs and torso; in a healthy person the surface of both legs and torso amounts to 54% of the total body surface (17). Consequently, an estimation on the increase in BMI simulated by the polymer flap could be calculated from the weight increase by an additional layer simulating fat tissue as it covers 50% of the volunteer body surface. Multiplication of 50% of the average total body surface (in cm^2) by 1.6 cm layer thickness of 1.15 g/cm^3 density led to a simulated increase in BMI of 5 kg/m^2 for the three volunteers. The feedback monitor signals were expressed as mean ± standard deviation and compared to those of the same volunteer without the polymer flap. A paired-samples t-test was used in the statistical analysis (SPSS v.22 (IBM); differences were considered statistically significant for $P < 0.05$).

Experiment 4: Positioning of the transducer array

All tests above were performed with the volunteer positioned supine. In clinical setting patients are positioned both prone, supine and sideways. In case a patient is positioned prone the transducer should be fixed to the back of the patient for patient-comfort reasons. For three volunteers both positions were evaluated: the transducer was applied to the back while positioned prone and on the front while positioned supine. The monitor signal intensity for both positions was retracted from the LabView data and compared. Results were expressed as means ± standard deviations. Statistical analysis involved a paired-samples t-test (SPSS v.22 (IBM); differences were considered statistically significant for $P < 0.05$).

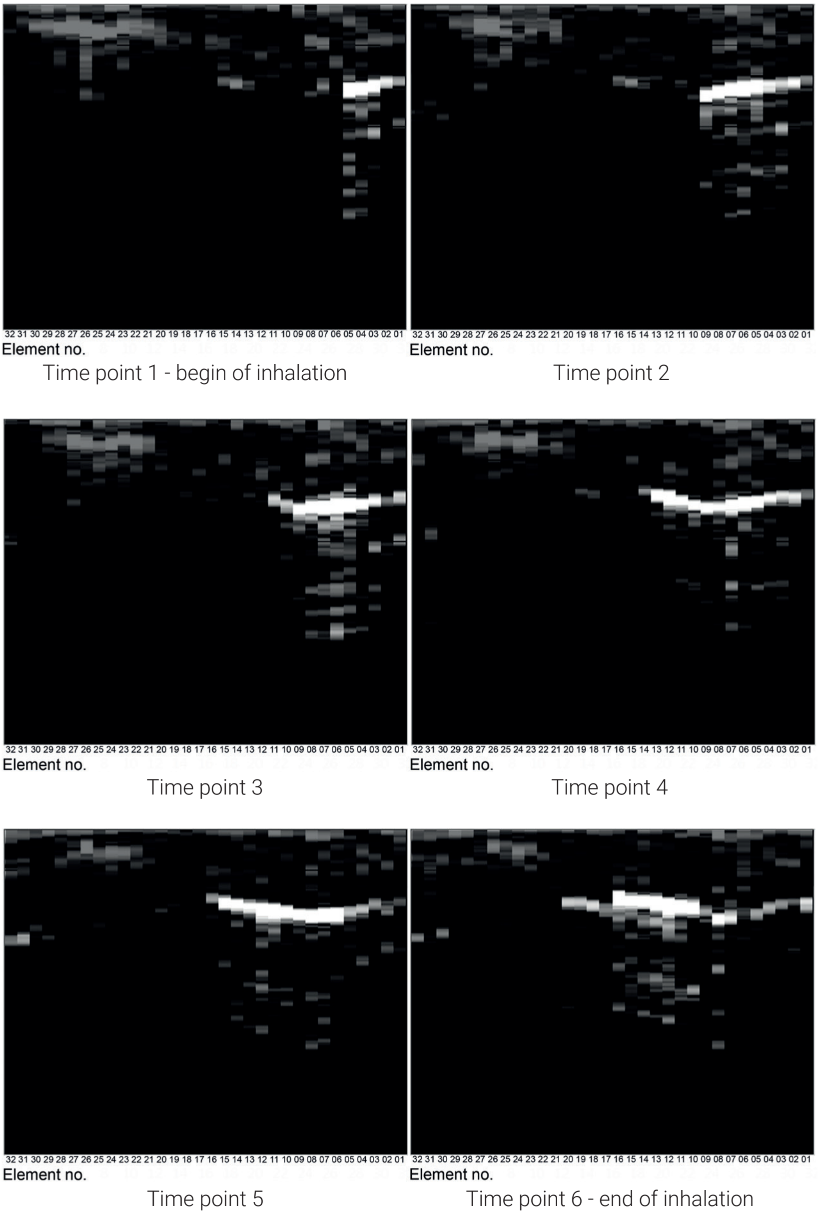

Figure 6.3: *Images of the breathing signal on the feedback monitor. The bright echogenic pleural line expands from right in the screen from time point 1 to element no. 21 in time point 6, this movement visualizes one inhalation by one of the volunteers. During exhalation the diaphragm relaxes and the pleural line signal is contracted back to time point 1.*

RESULTS

The respiratory motion was visualized on the breath-hold monitor screen as a moving front along a horizontal line, putatively corresponding to the moving air-tissue interface from the visceral pleura as it passes the transducer elements during a respiration cycle. Figure 6.3 shows screenshots from the monitor during inhalation by one of the volunteers.

Experiment 1: Correlation of the breath-hold monitor signal to breathing motion

Figure 6.4 shows the time-dependent signals of the monitor and the M-mode recordings for one volunteer. A strong correlation was observed between the timings of the monitor signal at maximum expansion and minimum contraction and the diaphragmatic contractions as derived from M-mode ultrasonography (*Pearson r* = 0.91-0.99). This indicates that the breath-hold monitor signal is indeed a direct measure for diaphragm motion.

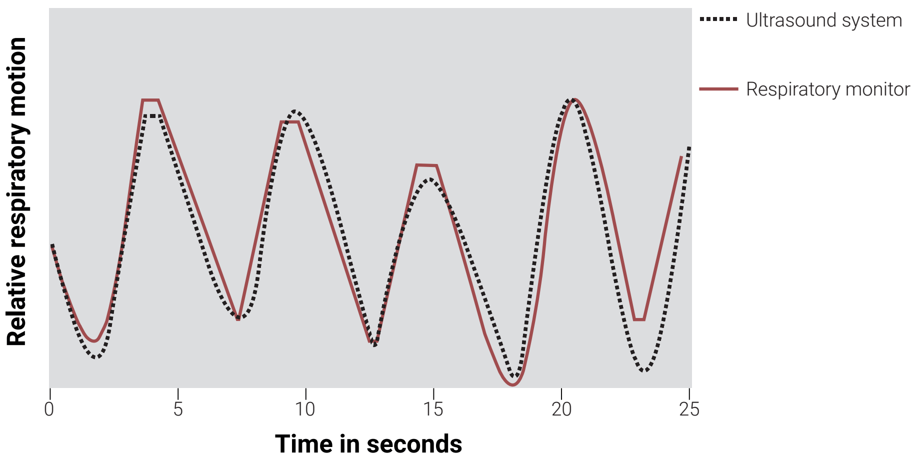

Figure 6.4: *The time-dependent signals of the monitor and the M-mode recordings are visualized for four inhalations and five exhalations. A strong correlation was found between the two techniques.*

Experiment 2: Accuracy of the breath-hold monitor

In three breath-holds where the volunteers were asked to maintain the same monitor output signal, the position of the pleural line was derived from concurrently recorded B-mode images. During a breath-hold the position of the pleura varied between 0.1-2.5 mm. The average position in the second and third attempts was compared to the first breath-hold and showed a median deviation of 2.8 mm (range 1.8-5.2 mm).

Experiment 3: Sensitivity of the breath-hold monitor signal to BMI

The mean pleura-signal intensity without polymer flap was 15.2 ± 1.4. By adding the polymer flap in between transducer and skin of the volunteer the mean signal intensity value increased to 17.8 ± 1.6, indicating a 17% loss of ultrasound reflectance signal. For all three volunteers the signal intensity was slightly affected by the presence of the polymer flap ($P = 0.002$). The resulting signal was still more than three times higher than the background noise.

Experiment 4: Effect of positioning of the transducer array

When positioning the volunteers in prone position and with the transducer array fixed to their back, the pleura-signal intensity as measured by the monitor was not different from that measured with the volunteers positioned in supine position and transducer array fixed to their chest (mean signal intensity of 15.2 ± 1.5 vs 15.3 ± 1.7; $P = 0.719$).

DISCUSSION

Accurate diagnostics and therapy in the imaging specialties, like interventional radiology, require that patients perform consistent levels of breath-holds repeatedly over an extended period of time, whereas for radiotherapy and nuclear medicine, patients need to produce consistent respiratory cycles over a period of time. Both aspects can be difficult for patients. The presented monitor visualizes in real-time the movement of the pleural line in a non-invasive manner, and was shown to provide a direct measure for the movement of the diaphragm. This technique should help patients to create a reproducible breath-hold or to maintain a consistent breathing pattern throughout the imaging sessions of the procedure.

The breath-hold monitor was capable in monitoring respiratory motion of the volunteers positioned both prone and supine. The mean signal intensity was slightly affected by a simulated change in body habitus of the volunteers. However, under these conditions the pleural line signal was still unequivocally readable from the monitor. Finally, this first version of the monitor demonstrates a median accuracy of 2.8 mm, attributable to the size of a single element of 3.5 mm, which is comparable to accuracies reported for other respiratory monitoring techniques (9, 18, 19). Even though the accuracy of the current prototype is already sufficient to produce a discerning signal, an even higher accuracy could possibly be obtained by increasing the number of elements per transducer. However, CT-guided punctures in a non-moving phantom model appears to also achieve accuracies of around 3 mm (20-22). Therefore, an increase in elements per transducer to achieve a higher accuracy might not result in a more accurate outcome, however this requires further investigation.

Main advantage of the monitor is that it uses a direct measure of the diaphragm motion, eliminating signal deformations between diaphragm motion and motion of external markers. A previously described breath-hold monitor employing a pressure-sensitive belt system increased the number of successful CT-fluoroscopy-guided biopsies on the first puncture attempt from 53% to 77% of the punctures (4). This latter technique, measured chest wall deformation only on the location of the belt. Therefore, we anticipate that biopsies using the breath-hold monitor presented in this paper will be at least as effective in terms of first-time success rate but possibly even more effective as the signal will be less susceptible to changes in breathing type. A limitation for both techniques is the sensitivity for the position. For both the belt and the transducer, a different signal is generated when the location is different to the original position. In applications in which planning scans and procedural scans are scheduled days apart, these respiratory monitors may not be as effective. None the less, many applications remain, from assisting image-guided needle punctures to minimizing image registration errors in PET-CT imaging and projecting breathing patterns to patients during radiotherapy.

Overall, the proposed ultrasound based breath-hold monitoring technique shows clinical potential. The prototype device has already proven to be an accurate, non-invasive and real-time respiratory monitor. Further work will be aimed at decreasing the size of the transducer elements and improvement of the monitor interface for easier signal interpretation.

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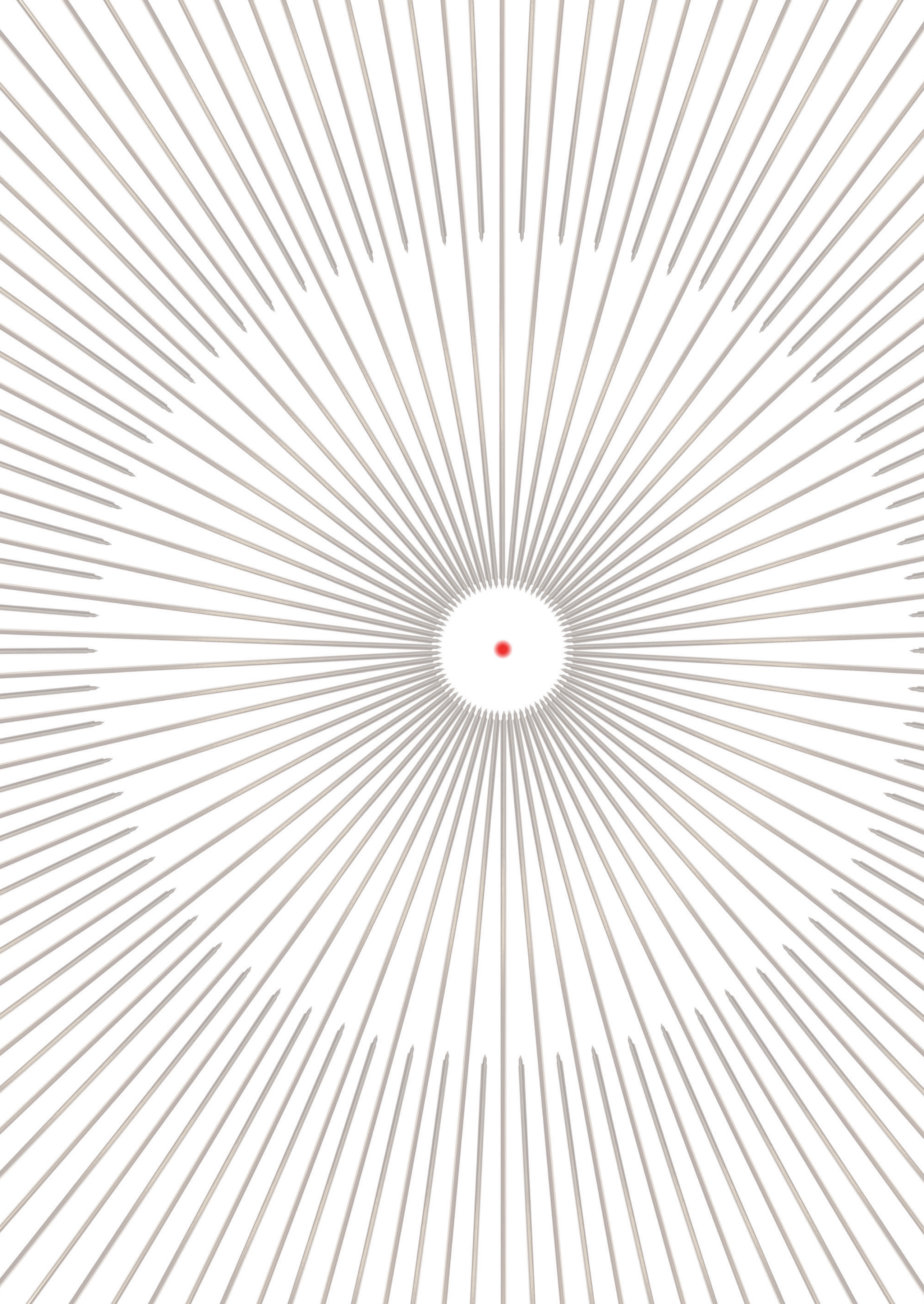

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Summary, discussion and future perspectives

SUMMARY

In this thesis the common theme is laser guidance. Laser guidance is used to visualize the planned needle path to a target, such as a lesion or tumour, for the operator during cone-beam CT-guided needle interventions. Visualization of the planned path allows the operator to advance the needle directly on course to the target without additional manipulations. Its successful application in the interventional angiography suite led to the assessment of laser guidance in CT-guided needle puncture training for radiology-residents. Lesions in the thoracic and abdominal regions are located in a moving environment making precise image guided targeting more challenging. To overcome the latter breathing effect, a breath-hold monitor has been developed to cope with respiratory motion.

C-arm cone-beam CT is a promising technique to guide complex needle interventions. The rotational capability of the C-arm with fluoroscopy provides the real-time feedback during the needle intervention. A consequential limitation of this technique is the lack of either depth or angular information of the actual needle position. In **chapter 2**, a phantom (patient simulation) study was performed with the purpose of assessing if a selection of needle guidance tools added to cone beam CT-guided needle interventions could assist the cone-beam CT guidance technology and consequently reduce the amount of guidance fluoroscopy; these needle guidance tools were compared to the freehand technique, i.e. without the aid of tools. From the selected guidance devices, laser guidance and the combination of needle holder and laser guidance were able to reduce the fluoroscopy time significantly compared to the freehand technique; a recorded decrease in fluoroscopy time of almost 40%. The effect of reducing the fluoroscopy time also had a positive effect on the registered hand dose for the radiologist. The measured hand dose for laser guided interventions was a factor 9 times lower compared to the freehand technique. This reduction is mainly attributable to the more efficient placement of the needle and reduced number of corrective needle manipulations in the entry point view. Laser guidance prevented direct exposure of the hands in the primary radiation beam.

The promising results of laser guidance in the laboratory setting resulted in a clinical study. In **chapter 3** laser guidance was used to assist the radiologist for 15 cone-beam CT-guided thoracic and abdominal biopsies. To assess the minimal gain, laser guidance was compared to relatively easy procedures selected from a dataset of retrospective freehand cone-beam CT-guided biopsies. The number of control scans was similar between the two guiding

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techniques and the procedure time was slightly shorter for the freehand technique. The results did show a significant reduction in fluoroscopy time for laser guidance, a reduction which was comparable to the reduction measured previously in the laboratory setting as detailed in **chapter 2**.

Chapter 4 shows the effect of laser guidance in a more complex needle intervention, namely radiofrequency (RF) ablation of osteoid osteoma using cone-beam CT guidance. Osteoid osteoma occur mainly in children and young adults, increasing the importance of an as low as possibly achievable radiation exposure. To reach the small nidus of the osteoid osteoma in bone an electric drill is used. However, the limiting space between C-arm detector and patient makes it challenging to position the drill according to the planning. Projecting the planned needle path using laser guidance with the C-arm rotated in the progress view could assist the operator to overcome these procedural challenges. For all 17 laser-guided RF ablations fluoroscopy time was reduced compared with the freehand technique. Within the selected similar degree of difficulty subgroup of 18 ablations in the hip-pelvic region, the reduction in fluoroscopy time was similar to the reductions seen in **chapters 2 and 3**. The procedure times were very similar between laser guided procedures and procedures using the freehand technique as were the numbers of cone-beam CT scans comparable.

Besides limiting fluoroscopy time during cone-beam CT-guided needle interventions, visualization of needle path planning could be a benefit for more operators performing image-guided needle interventions, especially the less experienced. In **chapter 5** the purpose was to assess if laser guidance could shorten the training and learning curve of radiology residents in CT-guided needle interventions. Fourteen trainees were divided into two groups to perform needle punctures using either laser guidance or the freehand technique in a phantom. Training was in four sessions at one week intervals. Each session entailed performing three simple and three difficult punctures. For the fourth session the trainees switched guidance technique to measure the effect of training. Results showed similar learning curves for both techniques in terms of needle placement time and accuracy. In case of laser guidance, the number of control CT-scans was significantly lower throughout the training.

Challenges for (cone-beam) CT-guided needle interventions are unintentional movement by the patient after acquisition and breathing motion during the interventions. A possible solution of the first problem is a vacuum mattress, while for the latter problem a new technique has been developed. In **chapter 6** a non-invasive technique is proposed to accurately visualize breathing motion by means of a feedback monitor to the patient. In a volunteer study, a small ultrasound transducer was positioned between the ribs to monitor the transition from visceral pleura to abdomen. Using the signals from the monitor the volunteer was able to repeatedly position a breath-hold on a similar level. The developed breath-hold monitor is still a first version with some limitations. However, this technique appears to accurately deal non-invasively with breathing motion by visualizing the movement of the visceral pleura to patients.

DISCUSSION

The number of image-guided percutaneous needle interventions has grown rapidly since the first performed CT-guided biopsy in 1975 (1). With the increasing number of needle interventions, the complexity and challenges also increase (2). These complex needle interventions often require planning to ensure success (3). The cone-beam CT guidance technique offers the option of needle path planning and guidance (4). Challenges in cone-beam CT-guidance are to position the needle along the planning without switching too often between the fluoroscopy guidance views, entry point and progress view, and to limit the fluoroscopy guidance during needle manipulations.

The studies presented in this thesis have shown that laser guidance for cone-beam CT-guided needle interventions reduces the fluoroscopy time significantly. Visualizing the needle path planning using a laser pointer resulted in a more efficient needle placement and prevented direct exposure of the operator's hands to the primary radiation beam. At present one of the angiography suite vendors has a built-in crosshair laser in the detector housing of the C-arm (5). However, in progress view with the C-arm rotated perpendicular to the needle path planning, the laser in the detector housing is unable to assist the radiologist and as discussed in **chapter 4** the distance between detector and patient can become challenging for needle guidance, this might limit this laser guidance technique. Electromagnetic and optical navigation systems have the ability for performing the procedure without any fluoroscopy guidance. However, fluoroscopy has the advantage of providing a quick comparison on progression and anatomical landmarks visible in the fluoroscopy image instead of obtaining a new cone-beam CT-scan.

Reducing the use of fluoroscopy reduces the radiation dose to patient and radiologist. Laser guidance limited the use of fluoroscopy guidance in the entry point view, effectively preventing direct exposure of the operator's hands in the primary radiation beam. An additional tool that can be used is iSYS (Interventional Systems; Austria), a table-mounted remote-controlled needle holder. This holder saves the radiologist from direct radiation exposure by using the remote control option for the needle holder (6). However, a drawback for the patient is that fluoroscopy is used to align the needle holder in the correct position. The development of asymmetrical collimation will provide the possibility to further lower the dose for both patient and radiologist. Pre-sets for cone-beam CT-guided needle interventions should be investigated, making automatic collimations possible. For example, automatic collimation to a radius of 3-5 cm around the bulls-eye in the entry point view and a 2 cm radius around the needle path planning in the progress view. By using the asymmetrical collimation in such a manner it will reduce the contribution of fluoroscopy to the exposure to patient and medical staff substantially.

Laser guidance did not have a significant impact on reducing the procedure times. **Chapter 2** shows that laser guidance increased the procedure time by 1 to 2 minutes, while in **chapter 5** the radiology-residents reduced the difference in procedure time between laser guidance and freehand technique to zero after training. In complex needle interventions the slightly extra time required in preparation and positioning of the laser unit was lost in the wide range of the recorded procedure times. When compared with other guidance devices, the extra procedure time produced by laser guidance is minimal (6-8).

No difference was found in the number of control scans between freehand technique and laser guidance for cone-beam CT needle interventions. Needle path visualization by laser pointer and/or fluoroscopy imaging provide the needle positioning verification. During conventional CT-guidance a control scan is the only technique to verify the needle position. This is the main reason for requiring more scans in conventional CT guidance in comparison to cone-beam CT guidance (9). In **chapter 5** the trainees in the freehand group showed a similar result of three control scans from the beginning to the end of the training. The trainees in the laser group needed however only one control scan and achieved this result without any fluoroscopy guidance.

Overall, laser guidance prevents exposure to the hands of the radiologist, reduces fluoroscopy time, maintains tactile feedback and facilitates accurate needle placement. By using data from Table 1.1 (**Chapter 1**), a small selection of guidance devices and navigational systems currently available have the capability of reaching similar results. These devices, however, are in a higher price category. In addition, the strength of this laser guidance device is its simplicity in use and the direct visualisation of the planning to the radiologist. Laser guidance requires no registering of previous scanned image volumes to the patient (10), table mounting (6) or transfer of image volumes to other needle planning systems (11). Furthermore, setting up laser guidance in a sterile environment is completed within a few minutes.

The needle path planning used in laser guidance is based on the obtained (cone-beam) CT, meaning the planning does not take patient motion and breathing motion into account. Breath-hold instructions can be applied, but the success of an accurate needle placement often not only depends on the skill of the radiologist but also the patient's compliance. Our novel respiratory monitor could possibly assist in resolving the issue of patient compliance. Our developed breath-hold device shows to be accurate but requires further improvement before testing in a clinical setting. A double adhesive gel pad is necessary for simple fixation to the patient's skin. The presented signals to the patient on the feedback monitor could be more simplified. Modifications to this end will show the signal in colour with a link to the reference breath-hold level. This means that during breathing the signal changes colour depending on the correlation to the reference breath-hold. A colour change from red to orange (close to the reference breath-hold level) to green (the reference level).

FUTURE PERSPECTIVES

The advances in the interventional oncology field (12) has led to the rapid development of new image-guided interventions for the local treatment of tumours (13). Together with the quest for more minimally invasive procedures, the pace of the introduction of the hybrid OR (an operation room including a C-arm angiography system with cone-beam CT capabilities) in hospitals has quickened. In 2011 the first hybrid OR was installed in the Netherlands. Currently 21 hospitals are equipped with hybrid OR's, and this number may double in the next three years. This means that many hospitals in the Netherlands have the capability to perform these complex percutaneous needle interventions using cone-beam CT guidance.

Laser guidance has shown to be able to reduce fluoroscopy times by visualizing the planned needle path. The strength of laser guidance compared to many other guidance devices and navigation systems is its simplicity in visualizing the planned needle path. During the puncture the radiologist can keep his/her attention on the patient, instead of the fluoroscopy visualizing monitors. However, despite the simplicity and effectiveness of the laser technology widespread implementation could be hampered by arguing that the system cannot as yet be seamlessly integrated into the cone-beam CT guidance; it is an extra device in the angiography suite requiring extra steps in the workflow. A preferable development would be a further integration of the laser inside the cone-beam CT's own guidance system. For example automatic transfer of the angles to the laser system from the needle path planning software. This is a development which can only be realized in cooperation with the vendors of the C-arm systems. An example of such a collaboration is Brainlab with Siemens Healthineers; the Brainlab navigation system automatically registers the cone-beam CT scan to their system and patient, saving valuable procedure time (14).

As mentioned previously, complex needle interventions, like ablation therapy, are procedures that are preferably performed in the angiography suite and hybrid OR. These rooms are designed for procedures under sterile conditions, personnel involved are specifically trained and the C-arm offers a better working space compared with the CT-scanner (15). Recently the cone-beam CT-guidance software (XperGuide; Philips Healthcare, Best, The Netherlands) was updated with an ablation therapy planner (9). This software allows planning an ablation needle to superimpose the ablation area, which is manufacturer-specified, over the segmented tumour. The provided information could assist in determining the numbers of ablative needles necessary and therefore the size of the lesion, how to position these needles so as to obtain both a safe ablation zone and a complete coverage of the tumour to overcome under-treatment.

A different development is the use of augmented reality for needle guidance, the fusion of real world and virtual data in a single view. In 2012, Gavaghan et al. (16) showed the possibilities of a miniature projector, coupled to an optical tracking navigation system, of projecting the target entry point, needle alignment and needle depth directly on the patient skin while in real-time adapting the projections to the progressing needle. New developments from Philips Healthcare have integrated this technique in cone-beam CT guidance software (17). Instead of using a projector, four optical video cameras were mounted inside the detector of the C-arm. Optical markers on the patient made it possible to project the needle path planning and cone-beam CT information inside the video feeds, which were projected on one of the in-room monitors. With this technique the fluoroscopy guidance is no longer necessary in the entry point view, a development we also pursued with laser guidance. Disadvantage of this technique is the presented visual feedback on the monitors. Meaning, the radiologist is required to switch his/her attention between patient and monitor during the procedure. An obvious next step in the development of augmented reality would be the integration of holographic glasses, like the Microsoft HoloLens, to the procedure which would make it possible to visualize the planned needle path as a hologram, without the need for guidance device preparation, positioning and registration.

CONCLUSION

To conclude, laser guidance is an advanced guidance technique which has accomplished simplification of the image-guided needle intervention, with especially important implications for decreasing and restricting the exposure to damaging radiation of both patient and operator, and other personnel involved in needle guided interventions. Combining laser guidance and the breath-hold monitor holds for the near future the prospect of the availability of a complete state-of-the-art “system” to assist the radiologist in performing image-guided needle interventions in the thorax and upper-abdomen area.

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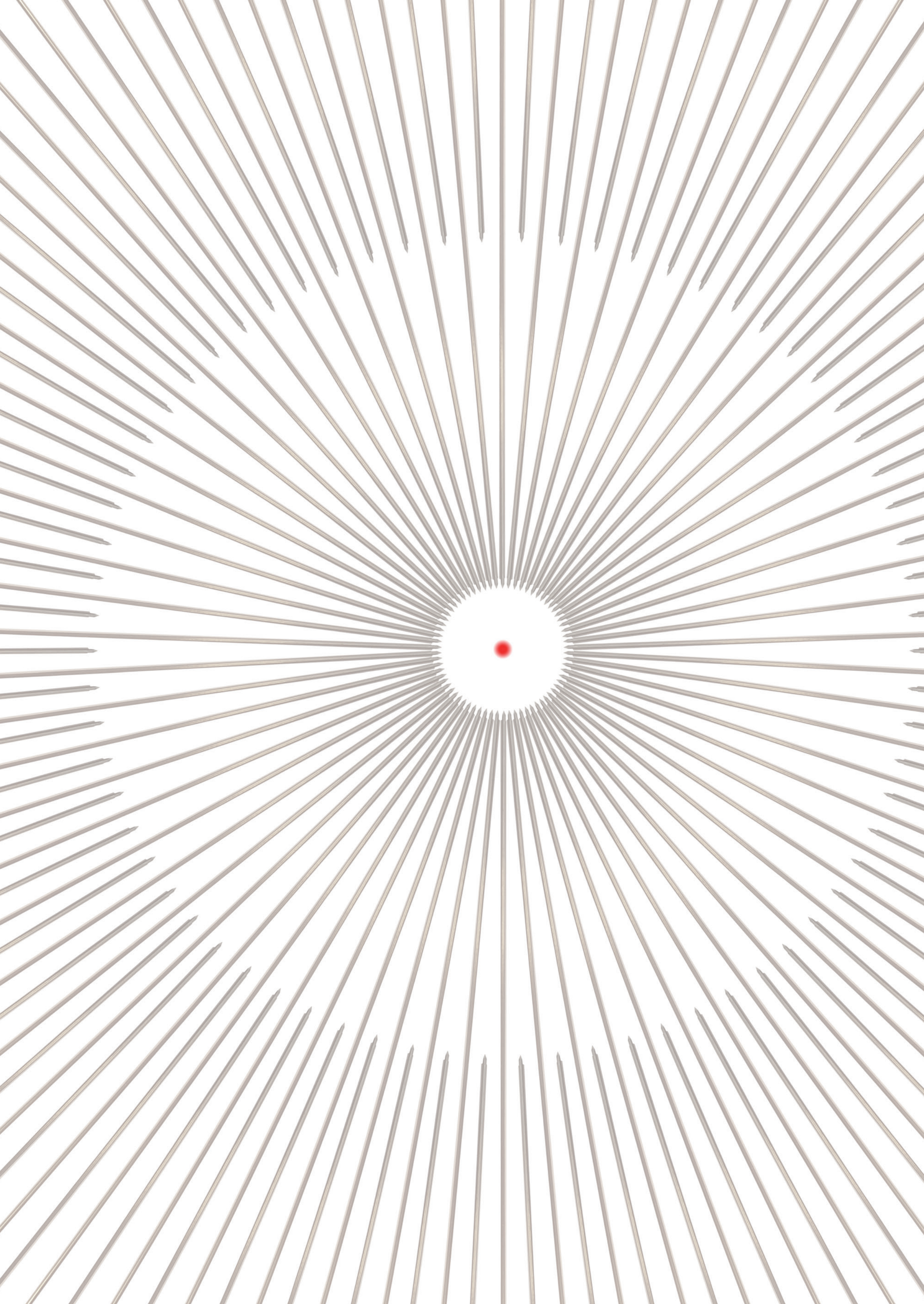

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Nederlandse samenvatting (Summary in Dutch)

SAMENVATTING

Het gemeenschappelijke thema van dit proefschrift is laser geleiding. Laser geleiding wordt gebruikt om het geplande naald pad in de richting van de target, zoals een laesie of tumor, te visualiseren voor de radioloog tijdens cone-beam CT geleide naald interventies. Door de naald pad planning te visualiseren kan de radioloog de naald direct in de richting van de target plaatsen zonder hiervoor extra naald manipulaties nodig te hebben. Het succes van het laser systeem in de angiografie kamer leidde tot de evaluatie van laser geleiding tijdens CT-geleide naald interventie training voor radiologie-assistenten. Het accuraat plaatsen van naalden in verdachte thoracale en/of abdominale laesies wordt bemoeilijkt door de bewegelijke omgeving waarin de laesies zich bevinden. Om voor deze ademhalingsbewegingen te corrigeren is er een ademhalingsmonitor ontwikkeld welke de beweging in beeld kan brengen.

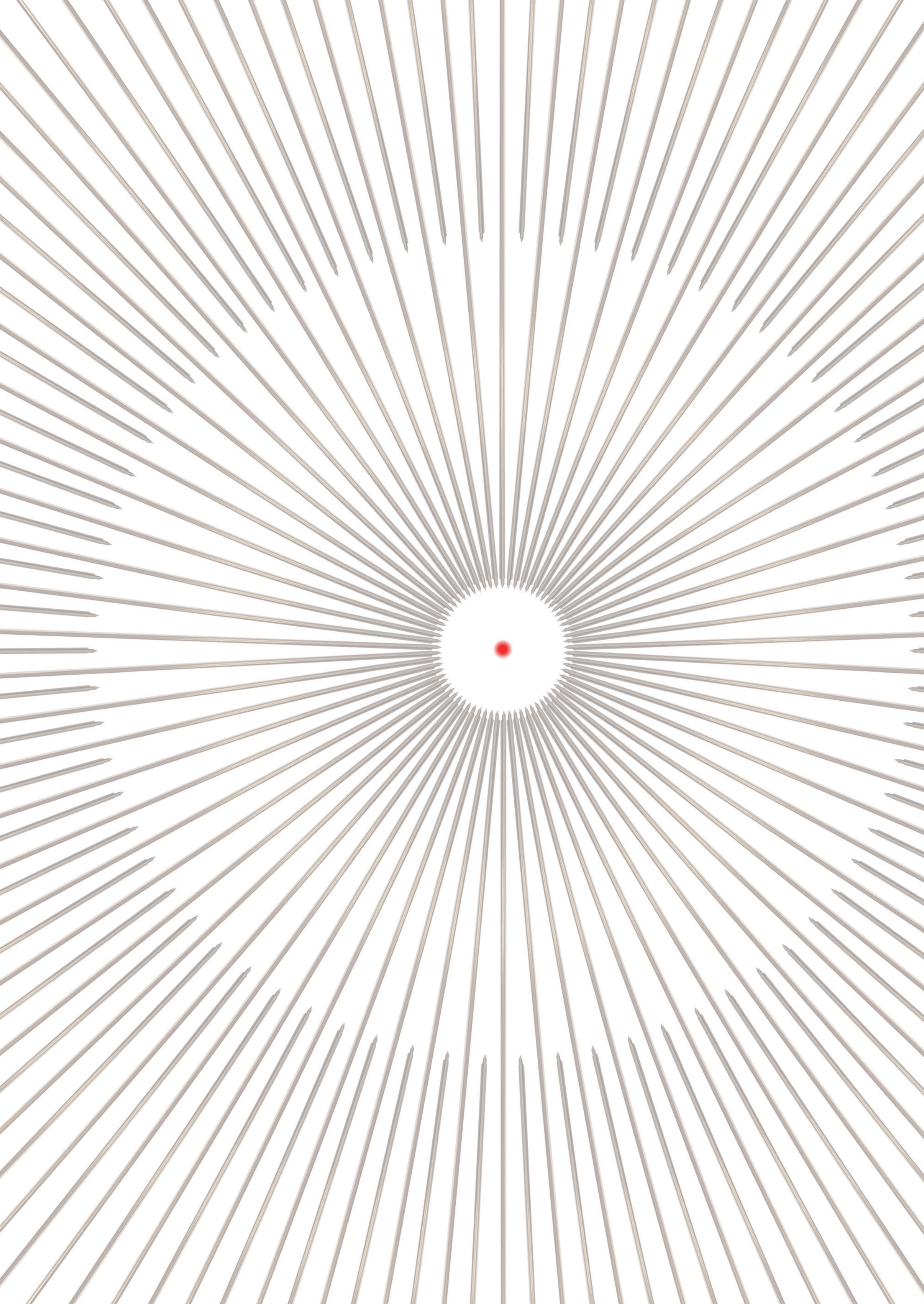
Cone-beam CT voor C-boog is een veel belovende techniek voor het geleiden van complexe naald interventies. De rotatie mogelijkheden van de C-boog met de doorlichtingsmogelijkheden geeft de mogelijkheid tot real-time terugkoppeling van de positie van de naald-tip tijdens de interventie. Een limiterend gevolg is het gebrek aan of diepte of hoek informatie van de actuele naald positie. In **hoofdstuk 2** werd er een patiënt simulatie studie uitgevoerd met als doel het beoordelen of een selectie van naald geleidingsinstrumenten een toegevoegde waarde had voor de cone-beam CT geleide naald interventies en daarnaast in staat waren om de lengte van de doorlichtingstijden te verkorten. Deze naald geleidingsinstrumenten werden vergeleken met de conventionele "freehand techniek", het plaatsen van naalden met de vrije hand zonder gebruik te maken van extra instrumenten. Van de vooraf geselecteerde instrumenten waren laser geleiding en de combinatie van laser met disposable naald houders in staat om de doorlichtingstijden significant te verlagen ten opzichte van de freehand techniek; een verlaging van bijna 40% werd gerealiseerd. Het verkorten van de doorlichtingstijden had ook een positief effect op de registreerde stralingshanddosis voor de radioloog. De gemeten handdosis voor laser geleide naald interventies was een factor 9 keer lager in vergelijking tot de handdosis gemeten bij de freehand techniek. Deze verlaging is voornamelijk toe te schrijven aan de efficiëntere naald plaatsing en de gereduceerde hoeveelheid aan naald manipulaties in de entry point view. Laser geleiding voorkwam dus directe blootstelling van de handen in de primaire stralingsbundel.

De veel belovende resultaten uit de patiënt-simulatie studie resulteerde in een klinische studie. In **hoofdstuk 3** werd laser geleiding gebruikt voor het assisteren van de radioloog bij 15 cone-beam CT geleide thoracale en abdominale biopten. Om het minimale effect te meten werd laser geleiding vergeleken met relatief eenvoudige procedures geselecteerd uit een dataset van retrospectieve cone-beam CT geleide biopten freehand uitgevoerd. De controle scans aantallen waren vergelijkbaar tussen beide groepen en de procedure tijd was korter voor de retrospectieve groep. De resultaten lieten echter ook zien dat er een significante verlaging was voor de doorlichtingstijden bij gebruik van laser geleiding. Een procentuele verlaging vergelijkbaar met het percentage gemeten in de patiënt-simulatie studie uit **hoofdstuk 2**.

Hoofdstuk 4 laat het effect van laser geleiding zien in een complexe naald interventie, namelijk radiofrequente (RF) ablatie van osteoid osteomen geplaatst onder beeld gestuurde geleiding van cone-beam CT. Osteoid osteomen komen voornamelijk voor bij kinderen en jong volwassenen, wat het belang van een zo laag als mogelijke stralingsdosis nog extra voorop stelt. Om de kleine nidus van de osteoid osteoma in het bot te bereiken wordt gebruik gemaakt van een elektrische boor. Echter, door de gelimiteerde ruimte tussen C-boog detector en patiënt is het veelal een uitdaging om te boren volgens de naald pad planning. Door de planning te visualiseren met laser geleiding en de C-boog te positioneren in de progress view wordt de radioloog geassisteerd door zowel de laser als de doorlichting om de boor correct te positioneren. In vergelijking met de freehand geboorde trajecten waren de doorlichtingstijden verlaagd wanneer er tijdens de procedures laser geleid werd gewerkt. Binnen een subgroep van 18 RF ablaties, allen met osteoid osteoma in de heup-pelvis regio en een zelfde moeilijkheidsgraad, was wederom het percentage van gereduceerde doorlichtingstijden voor de laser geleide procedures vergelijkbaar met de percentages beschreven in **hoofdstuk 2 en 3**.

Naast het zoveel mogelijk limiteren van het doorlichtingsgebruik tijdens cone-beam CT geleide naald interventies zou het visualiseren van de naald pad planning ook een voordeel kunnen zijn voor andere gebruikers welke beeld gestuurde naald interventies uitvoeren, en dan voornamelijk de minder ervaren gebruikers. In **hoofdstuk 5** was de vraagstelling of laser geleiding de training en leercurve van assistent-radiologen in CT-geleide naald puncties kon verkorten. Veertien assistenten werden verdeeld over twee groepen om CT-geleide naald puncties uit te voeren in een fantoom met of laser geleiding of door gebruik te maken van de freehand techniek. De training werd gegeven gedurende vier sessies, elke sessie met een interval van een week er tussen. Tijdens elke sessie werden er drie simpele en drie moeilijke puncties uitgevoerd. In de vierde sessie wisselden de assistenten van techniek om het effect van training te meten. Als resultaat werd er een vergelijkbare leercurve gemeten tussen beide technieken, laser geleiding en freehand techniek, voor zowel de naald positioneringstijd als de accuraatheid van de naald plaatsing. In het geval van laser geleiding waren een significant minder aantal controle CT-scans nodig gedurende de gehele training.

Accidentele bewegingen van de patiënt na acquisitie en ademhalingsbewegingen tijdens naald interventies kunnen beeldgeleide naaldinterventies complex maken. Een mogelijke oplossing voor het limiteren van de bewegelijkheid van de patiënt is door gebruik te maken van het wel bekende vacuüm matras. Voor de ademhalingsproblematiek is er een nieuwe techniek ontwikkeld om accuraat ademhalingsbeweging te visualiseren en deze informatie via een terugkoppeling aan de patiënt te presenteren. In **hoofdstuk 6** werd deze niet-invasieve techniek voorgesteld. In een studie met vrijwilligers werd een speciaal ontworpen transducer gepositioneerd op de huid, smal genoeg om tussen de ribben te plaatsen, om de transitie van het longweefsel naar het abdomen te visualiseren. Door gebruik te maken van de visualisatie van deze signalen, werd het voor de vrijwilligers mogelijk om herhaaldelijk een ademhaling vast te houden op eenzelfde niveau. De ontwikkelde ademhalingsmonitor is op dit moment nog een prototype met beperkingen, maar de techniek laat zien dat het accuraat niet-invasief om kan gaan met de ademhalingsbeweging door de beweging van het viscerale pleura te visualiseren aan de patiënt.



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Dankwoord (acknowledgements)
List of publications
Curriculum Vitae

DANKWOORD

Laser geleiding laat een zo ideaal mogelijk traject van naaldpunt naar target zien. De laser visualiseert hoe de naald in een rechte lijn naar het target dient te gaan. Hoewel ik met het onderzoek in dit boekje heb laten zien dat dit een efficiënte methode is, betekent dit niet dat de uitvoering van het onderzoek zelf in een gelijke strakke lijn naar het beoogde doel gaat. Een target omringd met rode cirkels zoals op de voorkant van dit boekje verdween nog wel eens van de horizon. Gelukkig sta je er in het onderzoek niet alleen voor en ben ik heel dankbaar voor alle hulp die ik hierbij heb gekregen. Dit heeft de onderzoeksjaren tot een fantastische tijd gemaakt. Graag wil ik iedereen bedanken voor hun begeleiding, steun, inzet en gezelligheid.

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LIST OF PUBLICATIONS

Peer-reviewed journals

Assessment of needle guidance devices for their potential to reduce fluoroscopy time and operator hand dose during C-arm cone-beam computed tomography-guided needle interventions
Kroes MW, Busser WMH, Fütterer JJ, Arntz MJ, Janssen CM, Hoogeveen YL, de Lange F, Schultze Kool LJ.
Journal of Vascular and Interventional Radiology, 2013 Jun; 24(6):901-906.

The use of laser guidance reduces fluoroscopy time for C-arm cone-beam computed tomography-guided biopsies
Kroes MW, van Strijen MJ, Braak SJ, Hoogeveen YL, de Lange F, Schultze Kool LJ.
CardioVascular and Interventional Radiology, 2016 Sep; 39(9):1322-1326.

Laser guidance in C-arm cone-beam CT-guided radiofrequency ablation of osteoid osteoma reduces fluoroscopy time
Kroes MW, Busser WMH, Hoogeveen YL, de Lange F, Schultze Kool LJ.
CardioVascular and Interventional Radiology, 2017 May;40(5):728-734

Laser guidance reduces the number of control scans in all phases of the learning curve in computed tomography-guided needle punctures: a phantom study
Kroes MW, Hoogendoorn SP, de Lange F, Hoogeveen YL, Schultze Kool LJ.
Submitted

Catching breath: monitoring respiratory motion directly using a novel ultrasound based monitor; a feasibility study
Kroes MW, Hoogeveen YL, de Lange F, Schultze Kool LJ.
In preperation

Conference proceedings

Hand dose assessment in combined cone-beam CT and real-time fluoroscopy guided needle puncture procedures using needle guidance devices
Kroes MW, Busser WMH, de Lange F, Hoogeveen YL, Schultze Kool LJ.
Electronic poster (C-1103), ECR 2011, Vienna, Austria

The effect of needle guidance devices on operator hand dose during needle puncture procedures with combined cone-beam CT and real-time fluoroscopy guidance
Kroes MW, Busser WMH, de Lange F, Hoogeveen YL, Schultze Kool LJ.
Oral presentation (No. 137), SIR 2011, Chicago, USA

The effect on operator hand dose of using needle guidance devices during cone-beam CT combined with real-time fluoroscopy-guided puncture procedures
Kroes MW, Busser WMH, de Lange F, Hoogeveen YL, Schultze Kool LJ.
Electronic poster (P-421), CIRSE 2011, Munich, Germany

Laser guidance reduces fluoroscopy time and radiation dose during needle interventions in the angio-suite
Kroes MW, Busser WMH, van Strijen MJL, Braak SJ, de Lange F, Hoogeveen YL, SchultzeKool LJ.
Poster presentation, NVvTG 2011, Woerden, the Netherlands

Laser guidance in combination with needle path planning reduces fluoroscopy time and patient radiation dose in cone-beam CT needle interventions
Kroes MW, Braak SJ, van Strijen MJL, Busser WMH, Hoogeveen YL, de Lange F, SchultzeKool LJ.
Oral presentation (No. 68), SIR 2012, San Francisco, USA

Laser guidance for (cone-beam) CT-guided needle interventions
Kroes MW, Busser WMH, de Lange F, Hoogeveen YL, Schultze Kool LJ.
Oral presentation, Norwegian Radiology Society Meeting 2012, Oslo, Norway

Towards a real-time diaphragm positioning system for aiding in needle interventions targeting small thoracic lesions
Kroes MW, de Lange F, Hoogeveen YL, Brabrand K, Hoff L, SchultzeKool LJ.
Poster presentation (LL-CHS-MO5A), RSNA 2013, Chicago, USA

Laser guidance reduces the number of control CT scans in all phases of the learning curve in CT-guided needle punctures: a phantom study
Kroes MW, Hoogendoorn SP, de Lange F, Hoogeveen YL, Schultze Kool LJ
Electronic poster (P-120), CIRSE 2017, Copenhagen, Denmark

Catching breath: a feasibility study to monitor respiratory motion directly using a novel ultrasound-based monitor
Kroes MW, Hoogeveen YL, de Lange F, Schultze Kool LJ
Electronic poster (P-562), CIRSE 2017, Copenhagen, Denmark

CURRICULUM VITAE

Maarten Willem Kroes was born on 9th of July 1985 in Deventer, the Netherlands. He grew up in Wilp, a small village in Gelderland and did his pre-university education at Etty Hillesum Lyceum in Deventer.

In 2004 he continued his education at the University of Twente in Enschede, where he studied Technical Medicine. During his masters, he specialized in Medical Robotics and Imaging for which he completed four internships at the departments of Nuclear medicine, Neurosurgery, Oral and maxillofacial surgery and Radiology all at the Radboud University Medical Center. In March 2011 he finished his graduation thesis entitled: "Needle guidance devices in the angio-suite: optimization of accuracy, radiation dose and puncture procedure time" which was the result of the research performed at the department of Radiology also at the Radboud University Medical Center.

The results from this research formed the basis of a research proposal written by Maarten, his supervisors Frank de Lange, Yvonne Hoogeveen and Leo Schultze Kool, and Nicolay Bérard-Andersen from NeoRad AS, the company behind one of the needle guidance devices from the graduation project. In September 2011 they received approval from the Norwegian Research Council for the application: "Method to improve percutaneous image guided interventions in the angio-suite" in the Industrial PhD scheme (Nærings-PhD). The result of this research lies before you. Next to the research, Maarten also worked as an application specialist for NeoRad AS.

Since October 2017, Maarten is working as Clinical Research Manager Interventional Imaging at Toshiba Medical Systems in Zoetermeer, the Netherlands.